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                  UNITED STATES DISTRICT COURT
 2
                  EASTERN DISTRICT OF NEW YORK
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 4 ROBERT A. FALISE, LOUIS KLEIN, )JR., FRANK MACCHIAROLA,
 5 CHRSTIAN E. MARKEY, JR. as
                                   )Trustees,
 6
                                    ) Plaintiffs,
                                                                     ) No. 99
 7
                                    )
                                         vs.
CV 7392
                                      (JBW)THE AMERICAN TOBACCO COMPANY,
8
                                    )
)
    et al.,
9
10
             Defendants.
11
12
13
                  CONTINUED VIDEOTAPED
            DEPOSITION OF DAVID M. BURNS, M.D.
14
15
                San Diego, California
                 Friday, June 9, 2000
17
                       Volume 2
18
19
20
21
22 Reported by:
23 RENEE KELCHCSR No. 5063
24 Job No. 109049
page 259
page 260
1
                  UNITED STATES DISTRICT COURT
 2
                  EASTERN DISTRICT OF NEW YORK
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  ROBERT A. FALISE, LOUIS KLEIN, )JR., FRANK MACCHIAROLA,
 5 CHRSTIAN E. MARKEY, JR. as
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 6
                                    )
                                        Plaintiffs,
                                                                     )
 7
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                                         vs.
CV 7392
                                      (JBW) THE AMERICAN TOBACCO COMPANY,
8
                                    )
)
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                                    )
                                             Defendants.
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14
15
          Continued videotaped deposition of DAVID M.
          BURNS, M.D., Volume 2, taken on behalf of
16
17
          Defendants, at 1515 Hotel Circle South,
18
          San Diego, California, beginning at 9:13 a.m.
           and ending at 5:36 p.m. on Friday, June 9,
19
20
           2000, before RENEE KELCH, Certified
21
          Shorthand Reporter No. 5063.
22
23
24
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page 261
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1
           San Diego, California, Friday, June 9, 2000
2
                     9:13 a.m. - 5:36 p.m.
 3
 4
                     DAVID M. BURNS, M.D.,
    having been previously duly sworn, was examined and
 5
 6
    testified as follows:
 7
 8
            MR. GRUENLOH: Mike Gruenloh, Ness Motley on
9
    behalf of plaintiff.
10
            MR. BERNICK: David Bernick for Brown &
11
    Williamson.
12
             MR. SCHROEDER: Tom Schroeder for R.J.
13
    Reynolds.
14
            MR. STEIN: Adam Stein for B.A.T. Industries,
15
    PLC.
16
            MR. PARSEGHIAN: Berj Parseghian for Philip
17
    Morris, Inc.
18
            MR. THOMPSON: Brent Thompson for R.J.
19
    Reynolds.
            MR. GRUENLOH: Mr. Bernick, at the end of the
20
    deposition yesterday you said you were going to attempt
21
22
    to get the judge -- or, I'm sorry, Magistrate Gold on
    the line this morning. What's going on with that? End
23
24
    the suspense.
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page 266 MR. BERNICK: What I've done is to contact 1 2 Judge Gold's chambers and determine his schedule for today -- he always tells me, and I've now seen, that he's a very busy guy -- to see if there's time when he 4 5 can take up problems that we have with the deposition. I'm told that he's available between 2:00 and 3:00 6 7 today, which as I do my arithmetic is between 11:00 and 8 12:00 this morning. 9 MR. GRUENLOH: Okay. 10 MR. BERNICK: So depending upon how things go, we'll see if we need to do that, my overwhelming 11 preference is not to do that. But I just can't tell how 12 the deposition is going to go. So that's the contact 13 14 I've had with the court's chambers. I've not spoken 15 with Judge Gold, himself. MR. GRUENLOH: Okay, thank you. 16 EXAMINATION (Continued) 17 18 BY MR. BERNICK: 19 Q Good morning, Dr. Burns. A Good morning. 20 In your report -- do you have your report here 21 22 in front of you? I don't know if that was marked as an 2.3 exhibit. 24 A I assume that it's probably in this list. page 266 page 267 Yes. I think Exhibit -- must be 1 Q 2 Exhibit Number 2. 3 Α 2 is what I have. 4 Q I'd like you to take a look at paragraph 10 of 5 your expert report in this case. 6 Does paragraph 10 of your report set out your 7 views as an expert on how scientific consensus is reached --8 9 Α 10 -- on the issue of whether smoking causes a 11 given disease? 12 A Yes. 13 And as I understand what you're saying in 14 paragraph 10, is that reaching a scientific consensus 15 involves a process; is that correct? A There are several ways that the term 16 17 "consensus" is used. There is a formal consensus 18 process, such as the ones that are used to generate the 19 Surgeon General's report. There is also the English 20 language use of that term, which is that the majority of 21 the scientific community has reached a conclusion, or 22 knowledgeable scientific community has reached a 23 conclusion on a given issue. 24 Q I'd like -- my question, I think asked you -page 267 page 268 1 I'd like to focus on the views that you have set forth in paragraph 10 of your report about how a scientific consensus is reached. And my question to you in 3 particular is whether those views include the view that 4 5 a process must take place? As I just described, I used the term in two 6 7 contexts. One is the formal process of reaching a 8 consensus such as that used by the Surgeon General's 9 report. And the other is the way that the term is used 10 as an English language term for the preponderant opinion

for the scientific community. One, the first, requires 11 a process. The second is something that is a state of 12 13 the art. 14 Is there anywhere in your report where you set Q 15 out any statement concerning how scientific consensus is 16 reached other than in paragraph 10? 17 A I don't believe so. 18 Focusing on paragraph 10, as you have described 19 how a scientific consensus is reached in paragraph 10, 20 does that involve a process? 21 MR. GRUENLOH: Objection; asked and answered. THE WITNESS: I have answered that question. 22 The use of the term in that paragraph is intended to 2.3 reflect a process used by the Surgeon General's report 24 page 268 page 269 which is, indeed, a process. 1 2 BY MR. BERNICK: 3 Q What paragraph 10 talks about is that a process 4 is performed by a set of expert reviews of the data; 5 correct? 6 A It describes the Surgeon General's process for 7 formation of scientific consensus, which is one of 8 preparations of drafts, review of those drafts, revision, re-submission for review, again revision, and 9 10 then submission to the Public Health Service for review, 11 and ultimately for clearance. Would it be fair to say that the statements 12 that you make in paragraph 10, the description in 13 14 paragraph 10 of your report relating to how consensus is 15 formed, is designed and only does cover what's taking place in connection with the Surgeon General's reports? 16 17 A It is intended to discuss the Surgeon General's 18 report process for forming consensus, that's correct. Q And does paragraph 10 fairly, in your view, 19 20 describe the process that has, in fact, been followed in 21 the course of issuing the Surgeon General reports? A I believe so, yes. 22 23 The -- you've referred to a consensus. 24 Consensus, as used in the English language, and as I page 269 page 270 understand your testimony, you believe that there are 1 2 other ways that scientific consensus can be reached 3 other than as described in paragraph 10; correct? 4 There are a variety of other processes, of Α 5 formal consensus formation. One of which was largely originated in 1970s, which is called formally a 6 7 consensus process. That has been widely used at NIH on various scientific and clinical topics. 8 9 So --10 There is also the -- a variety of other Α 11 approaches, such as that used by the National Academy of 12 Sciences and a variety of other organizations to achieve 13 a similar outcome to the Surgeon General's report. 14 Those are more or less formalized, depending on the organization. And then there is the general process of 15 16 scientific publication and review that leads people to 17 progress in their understanding of an issue 18 scientifically. 19 The only process for reaching scientific 20 consensus that you describe in your report is the 21 process followed by the Surgeon General; correct?

The process I described was one in this 22 23 paragraph, was the process used by the Surgeon General. 24 I refer to consensus elsewhere in the report, I believe, page 270 page 271 as to the English language use of the term as scientists 1 reading literature and reaching conclusions from it. 3 If you'd focus on the question. The question 4 asks for whether you have described the scientific 5 consensus process anywhere else in your report other 6 than in paragraph 10? 7 MR. GRUENLOH: Objection; asked and answered. BY MR. BERNICK: 8 9 Q I don't think we're communicating, Dr. Burns. 10 Paragraph 10 describes how scientific consensus is 11 reached, does it not, in conjunction with Surgeon 12 General reports? 13 A Paragraph 10 describes a consensus formation 14 process; that process used by the Surgeon General's 15 report. 16 Q Now I'm asking, is there any other place in 17 your report where you describe how scientific consensus is reached? 18 19 A There's no other place in the report where I 20 describe a formal process for achieving scientific 21 consensus. 22 Is there anywhere else in the report where you 23 set out the guidelines that are followed in reaching scientific consensus? 24 page 271 page 272 A I don't believe so. 1 Q Are there any other guidelines that you state 3 anywhere else other than your report -- strike that. Are there any guidelines that you describe 4 anywhere in your report for reaching scientific 5 6 consensus other than the quidelines that are set out in 7 paragraph 10? 8 A Well, paragraph 10 does not set out guidelines. 9 Paragraph 10 sets out a process that was used. It 10 describes the process the Surgeon General's report used. 11 It is not a set of guidelines or technical criteria for consensus formation. It simply describes the process 12 13 that was used. 14 Q Okay. Is there -- are there any guidelines or 15 standards for determining when consensus is reached on 16 the issue of smoking and health? 17 A There are multiple sets of those guidelines, 18 including ones that have been developed by various 19 organizations tasked with developing guidelines. There 20 are various groups that have internal processes for 21 examining this data. This data and other data. The 22 Surgeon General's process has a specific approach to 23 this, and much of that approach was conditioned by the 24 criteria defined in the 1964 report. page 272 page 273 1 Okay. The criteria defined in the 1964 report 2 are criteria for establishing causation? 3 A They are -- there is a discussion of how one 4 draws causal attribution from a variety of data on a 5 given topic. And there's a detailed discussion of both how that is done and the use of an examination of

7 epidemiologic data in that context. Q If you focus on my question. You said the word 8 9 "criteria." I simply asked you, are there criteria that 10 are set out in the 1964 Surgeon General's report on making a judgment on whether causation has been shown? 11 12 A I'm -- I guess I'm confused. I thought I answered your question. If you want me to take another 13 14 shot at it, if you want to try and clear it up. 15 Q No. I want you to tell me, yes or no, are 16 there criteria set out in the 1964 Surgeon General's 17 report for determining whether causation has been shown? A The 1964 report discusses the basis under which 18 a judgment of causality can be reached, and then lays 19 20 out a set of criteria for reaching a judgment. In 21 particular, it focuses on the kinds of criteria that can 22 be used for evaluation of epidemiological data in examining the question of whether causality has been 23 established. 2.4 page 273 page 274 MR. SCHROEDER: Would you mark that one, 1 please? Thank you. 3 BY MR. BERNICK: 4 Q The criteria that were used and described in 5 the 1964 report, are those criteria also set out in the 6 paragraph 10 of your report? A They're -- the terms that are used in paragraph 7 8 10 are similar to the headings for each of the discussions of criteria for the examination of 9 10 epidemiological data and causality. They are not the 11 sum total of that discussion within the Surgeon 12 General's report, but they are the terms that are used 13 for examination of epidemiological data in the context 14 of establishing causality. Q But just to be plain, there were five basic 15 16 criteria for making a judgment about causality in the 17 '64 report; correct? 18 We've now been through this three times. 19 You --20 Please answer the question, Dr. Burns. Are 21 there five criteria or not in the '64 report? MR. GRUENLOH: So I don't have to object every 2.2 23 time, I would like to place an ongoing objection for every time Mr. Bernick asks the question multiple times. 24 page 274 page 275 Go ahead and answer the question, Dr. Burns. 1 THE WITNESS: I've tried to make this clear 3 several times now. And I don't understand where the 4 confusion --5 BY MR. BERNICK: 6 Q There's a question before you, Dr. Burns. Are 7 there five criteria or not in the '64 report? 8 A The 1964 report lays out a set of approaches 9 for examining whether data can establish that a given agent, or exposure to a given agent causes a given 10 disease. Within that context -- within the context of 11 12 that discussion there is a detailed description of how epidemiological data can be used in that process. 13 14 Within that there are five criteria that are laid out 15 and discussed in some detail. The headings of those five criteria are the ones here in paragraph 10. 16 17 If I've not been clear in what I've said, and

it doesn't answer your question, please help me as to 18 19 where I'm not being clear and where that question is not 20 being answered, because I don't understand what more I 21 can tell you. MR. SCHROEDER: Mark that. 22 23 BY MR. BERNICK: 24 Q Did the Surgeon General in 1964 make a page 275 page 276 1 determination that based upon those five criteria, the epidemiological evidence, together with other evidence, was sufficient to make a judgment that smoking caused 3 disease? 4 I think you are mischaracterizing the 5 6 description in the Surgeon General's report. 7 Q Dr. Burns -- that's fine. A Okay. 8 9 Q Go ahead. 10 A The Surgeon General's report states very 11 clearly that one makes a judgment about causality from assembling all of the information and examining it. 12 13 They then go on to say that epidemiologic data is very important. And in order to examine epidemiological data 14 15 in the context of all of the data, you use these 16 criteria. 17 Are you aware of any statement prior to 1964 of 18 a scientific consensus on the issue of whether smoking 19 causes any disease? 20 A Yes. Q I want you to identify any statement prior to 21 22 1964 which sets out a scientific consensus of the 23 scientific community on whether smoking causes disease. 24 A There are several with increasing degrees of page 276 page 277 formality in terms of the process of consensus. Early 1 on there was an editorial in the New England Journal. That is an individualized expression of what that person 3 believes to be the consensus. Dr. Burney's statement in 4 5 the mid to late 1950s was done as the official act of the Surgeon General after reflection on the data, which 6 7 is another form of consensus. In 1962 there was a formal process conducted by 8 9 the World College of Physicians, which examined this 10 data and reached a formal judgment through a process of 11 examining all the data, that cigarette smoking causes 12 disease. Each of those can be described variably as a 13 consensus with increasing degrees of formality in the 14 process that they underwent to achieve the consensus 15 statement that came out. 16 Q When did the editorial come out of the New 17 England Journal of Medicine? 18 A I don't have a specific date from memory. My 19 recollection is that it was in mid 1950s; '55 or '56. 20 Q Dr. Burney's statement, when was that? 21 A That was in the late 1950s. I believe it was 1959, but it could have been '58 or '57. 22 23 Q And that was the statement that appeared in a publication, the Journal of the American Medical 24 page 277 page 278 1 Association? A You would have to show me it. He made a number

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of publications during that time.
 3
      Q Does this refresh your recollection?
 4
             MR. GRUENLOH: Do you have another copy of
 5
 6
     that?
7
             MR. BERNICK: No.
8
             MR. GRUENLOH: Are there going to be multiple
     documents that you don't have a copy of that you're
9
10
     going to be showing the witness today?
             MR. BERNICK: Maybe yes, maybe no. It depends.
11
12
             MR. GRUENLOH: As a courtesy, could you get
13 another copy of those, so I can review them?
             MR. BERNICK: I don't have time to make all
14
    those different copies. I don't think it will impair
15
16
    the examination.
17
             I'm just asking whether that refreshes his
18
   recollection that the statement that he said that Dr.
    Burney made, was made in 1959 in JAMA.
19
             THE WITNESS: I believe this is it, yes.
20
21 BY MR. SCHROEDER:
22
         Q The New England editorial was authored by whom?
         A I don't recall the author.
23
24
         Q Prior to the 1962 Royal College report, are you
page 278
page 279
1
    aware of any consensus statements of the scientific
    community on the causation issue that involved the
 3
    performance of a set of expert reviews?
        A Other than the ones that I have outlined thus
 4
    far, I'm not specifically aware of credible reviews that
 5
 6
    were conducted prior to then.
 7
         Q Okay. But in the ones that you've described so
8
   far, the editorial in the New England Journal, did that
9
    involve a set of expert reviews?
         A The New England editorial by definition is
10
     thought be to be an expert opinion.
11
12
         Q I didn't ask you that. I said --
13
             Well --
         Α
14
         Q -- did the editorial in the New England Journal
15 involve the performance of a set of expert reviews?
16
    A Perhaps you could define for me what you mean
17 by "set of expert reviews."
            Well, you used the words "set of expert
18
    reviews" in your expert report.
19
20
         Α
            I understand that.
         Q All I'm asking you, Dr. Burns --
21
22
         A I understand that, but you're telling me that
23
     every time I try to use it as --
        Q Excuse me. I try to not to interrupt you. I
page 279
page 280
    know that's very hard for me.
1
 2
         A Go ahead.
 3
            Could I have the same courtesy? However you
 4 use the word -- or words "set of expert reviews" in your
 5
    expert report, Dr. Burns, did the editorial in the New
    England Journal involve a set of expert reviews?
 6
 7
             MR. GRUENLOH: Object to form.
             THE WITNESS: As I have made plain now
 8
    innumerable occasions, that terminology in my report
 9
10
    describes the Surgeon General report's process. The
11 first report that used that process was the 1964 report.
12 Okay? Therefore --
    BY MR. BERNICK:
13
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I understand --14 15 -- by definition there was no report prior to Α 16 the first one which was released in 1964. 17 Q My question for you, understanding that you were intending to describe in your report the Surgeon 18 19 General reviews --20 Α Yes. 21 -- the Surgeon General reports, I'm simply 0 22 asking about whether some of the characteristics that 23 you pick out for that expert review, for that consensus 24 process, were in existence prior to 1964. And the first page 280 page 281 one that I've picked out is "set of expert reviews." 1 2 So my question to you is very simple. Did the editorial that appeared in the New England Journal that 3 you had reference to, did that involve the performance 4 of a set of expert reviews? 5 A I would assume that it did. Okay? 6 7 Q Do you know that it did? A Please let me finish my answer. 8 9 Sure. Okay? The normal process by which an editorial 10 Α 11 appears in the New England Journal is that the editors 12 of that journal ask someone to write it. It is then 13 reviewed by an external set of experts, and then it is 14 published. That is the process by which an editorial appears. Therefore, it would have undergone a set, more 15 than one, of expert reviews of its content. Is that a 16 17 process comparable to the Surgeon General's process, 18 with all its detailed checks and balances? No, it is 19 not. It's a much more limited process, but it is one 20 that is a process. Did the set -- did the editorial that appeared 21 in the New England Journal use or apply the criteria for 22 23 assessing epidemiological evidence that are referenced 24 in your expert report? page 281 page 282 1 Not explicitly. They used the criteria used in 2 the Surgeon General's report of defining judgment based on an integration of all of the data that existed. They 3 did not formally apply the specific criteria in 1955 4 5 that had not been developed prior to the 1964 report in 6 its form as described in paragraph 10. 7 Are you saying that the criteria for assessing 8 epidemiological evidence that appear by name in 9 paragraph 10 in the 1964 report had not been developed prior to the 1964 report? 10 11 A No. No. I'm saying that the 1964 report 12 formalized them in a very specific way. They are drawn 13 from prior considerations, particularly the Bradford 14 Hill criteria, among others, that had been discussed in 15 the literature prior to that time. 16 Well, then let me come back to my question. Do 17 you know the editorial that appeared in New England 18 Journal actually applied the criteria for assessing 19 epidemiological evidence as those criteria are 20 referenced in your expert report? 21 The criteria that are referenced in my expert 22 report first appeared in 1964 in the Surgeon General's 23 report. There was a scientific and philosophical 24 discussion about the termination of causality that

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page 282
page 283
1 antedated that in the scientific literature, including
   the development of criteria by epidemiologists such as
 3
    Bradford Hill.
             I'm just asking you, do you know what criteria
 4
    were applied to the epidemiological data in the
 5
     editorial in the New England Journal?
 6
 7
          A I am trying to answer your question.
8
            Tell me what criteria were actually applied in
     the assessment of causation that appeared in the New
 9
     England Journal. Do you know?
10
         A The criteria of integrating scientific
11
12
     information to form a reasoned judgment.
13
          Q Is that it?
14
             There were no formal criteria laid out in that
    editorial. You're asking -- I mean, I don't understand
15
    what -- what you're doing. You're asking me for formal
16
17
    criteria in an article that doesn't have formal criteria
18
    laid out. You're then asking me what criteria are used.
    When I give you the criteria that are used, you don't
19
20
    want to accept those. I don't know where to go with
21
22
             MR. SCHROEDER: Mark that.
23
     BY MR. BERNICK:
            Well, are you or you not saying that there were
page 283
page 284
     formal criteria for causation that were set out in the
 1
 2
     editorial that appeared in New England Journal? Yes or
 3
 4
            I'm saying that the person who wrote the
 5
     editorial in the New England Journal was, indeed, a
     scientist who was familiar with the process
 6
7
     scientifically of drawing causal inference from data.
    That individual did not feel compelled to write down as
8
9
     explicit criteria the criteria that they were using in
    the formation of that judgment. And therefore, that
10
11
    component of the process that they used was not included
12 in the text of that editorial. That is not to say that
13 that individual was not trained in and did not use a
    scientific process for assembling data to form a
14
     judgement about whether cigarette smoking caused lung
15
16
    cancer.
            Dr. Burney's official statement that you say
17
18 was made in the 1959 JAMA article, did that involve the
19
    performance of a set of expert reviews?
20
          A It is my understanding that that article was
21
    generated within the Public Health Service, within the
22
    office of the Surgeon General, and in that setting would
23
     have undergone a substantial number of expert reviews
24
     prior to its submission to the journal. The journal
page 284
page 285
    would also have subjected it to a set of expert reviews.
         Q Is that the -- is that the kind of expert
 2
     review that took place in connection with the '64
 3
 4
    report, or is that a different kind of expert review?
 5
         A That is the kind of expert report -- expert
 6
    review that occurred in conjunction with the preparation
 7
    of an official position of the Public Health Service.
    That is similar to, but nowhere near as extensive, as
     the process that occurred in '64 and subsequently with
```

the production of a formal Surgeon General's report. But it is, indeed, similar in the sense that it involves input from multiple extremely knowledgeable individuals in various parts of the government. And then it's subjected to an external review as part of the process of being published.

Q Did Dr. Burney set out formal criteria for causation when he issued his statement in 1959?

A I believe that Dr. Burney in his 1959 statement used the standard approach to establishing scientific causality, which was to assemble all of the information and reach a judgment. He did not feel compelled, nor did he describe, the specific, detailed philosophical criteria or scientific criteria that he used, nor did he assemble the data within the context of each of those

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2.2 23

24

criteria in order to do a formal proof of causality. The first time that I'm aware that that was done for smoking and health in that kind of exquisite detail was the 1964 report.

Are you aware -- strike that.

Was there, in fact, a consensus within the scientific community prior to 1964 about what the formal criteria were for reaching a judgment about causation?

There were a variety of criteria that were available. The -- and scientists had established a basis for defining a causal relationship for a great deal of time prior to that, particularly initially with experimental science, and also with derivative or non-experimental science, such as mathematics, where things are derived from basic proof.

The question that arose with the introduction of epidemiologic studies was how these studies which were intrinsically not experimental studies could be used to establish causal inference on the relationships of various characteristics in the population to disease inference -- to disease occurrence.

There were a series of criteria that were developed by individuals. I believe Dr. Lillenfeld developed some. The ones that are most commonly cited page 286 page 287

are those of Bradford Hill. All of those criteria were then examined and synthesized into the ones that were used in the 1964 report. Those criteria were principally intended to address the issue of how you integrate epidemiologic data with the more traditional controlled experimental data in order to derive causal inference.

- Q Prior to 1964 were there -- was there a scientific consensus on the formal criteria that should be used in reaching a judgment about causation using epidemiological evidence?
- There was an ongoing discussion with multiple sets of criteria that were in general widely accepted. Those criteria are the ones that I have described for you by Bradford Hill and by Lillenfeld. They were in evolution during that time, as was the acceptability of epidemiological data.

Okay. But there were widely accepted criteria for the use of epidemiologic data in drawing causal inference. That was something that was growing and

developing throughout that time and reached a 21 crystallization, if you will, with the '64 report. But 2.2 that is not to say that there was not a consensus prior 23 24 to that as to initially whether or not epidemiological page 287 page 288 data could be used, and if so, what kinds of criteria 1 would be used. 3 MR. SCHROEDER: Would you mark that one? 4 BY MR. BERNICK: 5 Q Are you aware of any consensus statement that 6 was issued -- strike that. 7 Are you aware of any statement that was issued reflecting the consensus of the scientific community on 8 9 the formal criteria that should be used for reaching a 10 judgment about causation based upon epidemiological 11 evidence? A I don't understand your question. Perhaps you 12 13 could clarify it for me. 14 Q You've described -- strike that. I'll just put it to you again. I'm asking for 15 whether there was a statement, a formal or any other 16 kind of statement, an article that came out, a statement 17 18 that was made, that reflected a consensus within the 19 scientific community prior to 1964 on the formal 20 criteria that should be used in reaching a judgment 21 about causation based upon epidemiological evidence? 22 Can you identify such a statement? A Other than the ones that I have identified by 23 24 Bradford Hill and Dr. Lillenfeld? I mean, those are page 288 page 289 1 formal statements. They were publications, okay? They --3 Talk --A They laid out criteria. You're asking me for 4 5 some group statement? 6 Q Yes. I'm asking for a statement that reflects a consensus of the scientific community on what those 7 8 formal criteria should be. Was there such a statement prior to the Surgeon General's report in '64? 9 A Well, you've asked multiple pieces there. 10 There clearly was a scientific consensus that 11 epidemiologic data could be used. There clearly was a 12 13 scientific consensus that there were ways to use it. 14 The formalization of that process, the 15 specifics as to how one would examine a body of 16 epidemiologic data, was codified by Bradford Hill and by 17 Lillenfeld and by others. Those -- I'm not aware of a 18 specific formal group that accepted the responsibility 19 for defining how that criteria would be used, okay, 20 prior to the criteria that -- or the process used in '64 21 by the Surgeon General's report. 22 Q Maybe I'm not being clear. I understand your 23 testimony that Bradford Hill wrote criteria. I 24 understand your testimony that Lillenfeld published on page 289 page 290 1 the subject. 2 What I want to know, was there any statement of 3 a consensus within the scientific community as to what 4 the formal criteria for causation should be based upon 5 epidemiological evidence?

The first public group that was tasked with 6 7 developing formal criteria for defining causality in the context of epidemiologic data for purposes of public 8 9 health, okay, that I'm aware of, the first formal process that went through with a public organization 10 11 that said, "This is something that we agree with," was 12 the 1964 Surgeon General's report. 13 Q Are you familiar with work that was done by 14 Dr. Bruslo (phonetic)? A I am. 15 16 Q Who is Dr. Bruslo? 17 A Dr. Bruslo was one of the early investigators 18 in tobacco and health who became director of health in 19 the State of California and dean of the school of art --20 of public health at UCLA. 21 Q Is he a person who was involved with this 22 process of developing criteria for causation? 23 A I have no knowledge of his specific contribution in that area. page 290 page 291 1 Q Do you know what his involvement was in the field of smoking and health? 2 3 A He published one of the very early 4 epidemiologic studies that showed that cigarette smoking 5 increased the risk of disease. Q And what's his area of specialty? 6 7 A His area of specialty is public health. If Dr. Bruslo were to have said as recently as 8 9 1996 that a new set of criteria for thinking about 10 disease causation were needed prior to the 1964 report, would that be a reasonable statement? 11 12 A That would depend on the context in which you are attempting to apply that statement. 13 Q Are you familiar with his retrospective review 14 of the significance of the Surgeon General's report in 16 1964? I'm not specifically familiar with that, no. 17 Q The Royal College report in 1962 of the 18 19 consensus statements that you've referred to prior to 1964, the Royal College's report in 1962 is really the 20 21 only one that actually involves a group of experts getting together to focus on the causation issue and 22 23 write a report of their findings; correct? 24 A It is the first report that I am aware of of a page 291 page 292 major organization convening an external group to specifically review the data and write a report on that 3 data. It is not the only group that has involved a 4 series of experts coming together to form a judgment, 5 but it is the first one that went through that kind of 6 formal process, sanctioned by an external -- by an 7 organization and involving individuals external to that 8 organization. 9 Now, the Royal College report actually came out before the Surgeon General's advisory committee was even 10 11 formed; correct? 12 That is correct. Α 13 Q And really actually what prompted the formation 14 of the Surgeon General's advisory committee was the issuance of the Royal College report; correct? 16 A I don't believe that that was a major factor in

defining the need for the Surgeon General's report. 17 18 understanding from discussions with people who were involved at that time was that the concern had been that 19 20 the science had become lost in the politics of the tobacco issue, and that it was important to define the 21 22 scientific base clearly and definitively in order to move public health forward. And that was the purpose of 23 24 the Surgeon General's report. page 292 page 293 1 Let me ask you this: At the time that the Royal College report had issued in 1962, isn't it true that the current statement of the Surgeon General in the 3 Public Health Service on the issue of causation was 4 5 still the statement issued by Dr. Burney in 1965 in the 6 JAMA article? 7 A I'm not sure what you're asking. There had been -- there had not been another formal statement 8 9 after that time. 10 Q Okay. That really was what I was trying to get at. Prior to the time the Surgeon General issued the 11 12 1964 report, the only statement of the Surgeon General on the issue of causation was the statement that 13 14 appeared from Dr. Burney in the 1959 JAMA article; 15 correct? 16 I think that's an unfair characterization. The 17 official statement was the one that was made in 1959. No official statement had been put out after that. 18 quite certain that there were other statements that were 19 20 made in speeches and in other publications, but they 21 were not formal positions, such as the one in '59. 22 Q So that the 1959 statement of Dr. Burney in the 23 JAMA article was the position of the Surgeon General, the formal position of the Surgeon General on the 24 page 293 page 294 causation issue until the '64 report was issued; fair? 1 A I think again that's a mischaracterization. 2 The way science works is that you develop a position 3 4 based on the data that exists in 1959 and you put that position out. It is then the position of the Surgeon 5 General based on the data that is available to the 6 Surgeon General in 1959. There was no review and 7 revision of that between 1959 and the '64 Surgeon 8 9 General's report, so there was not another statement. 10 That is not to say that the statement in 1959 reflected 11 all of the information that was available in 1963 or '4. 12 Q Well, isn't it a fact that the Surgeon General 13 was specifically asked to issue a new statement on 14 causation in 1962? 15 A The Surgeon General, I believe, was asked in 16 1962 to do that. 17 Q Okay. 18 A And because of the political context of tobacco 19 in the U.S. political environment, felt that simply a 20 statement by the Surgeon General as an agent of the administration would not be sufficient to satisfy the 21 22 political conflict that was going on. In that setting, the Surgeon General felt that it was more appropriate to 23 24 convene an external group that was independent and to page 294 page 295 have that external group examine the data and reach

conclusions and then submit that to the Surgeon General 2 rather than it being the position of the Surgeon 3 General, who is a branch, after all, of the 4 5 administration. Q Are you saying that Dr. Burney was not 6 permitted to make a new statement in 1962 politically? 7 A I don't think that's a fair interpretation of 8 9 the response I gave you. 10 Q Well, I wasn't seeking to interpret the 11 response. I'm trying to understand the facts. Are you saying that Dr. Burney was not permitted politically to 12 13 make a new statement about causation in 1962? A That wasn't what I said. 14 Well, do you believe that that's true, that 15 16 Dr. Burney was not permitted in 1962 politically to make 17 a new statement about causation? A I believe that Dr. Burney made a judgment that 18 19 the political environment was such that a statement by 20 the Surgeon General would not be one that would be the 21 most effective approach; that he felt that the most effective approach would be to convene an external 22 review. And that is what he chose to do. 23 Q Are you aware of any documentation of the 24 page 295 page 296 deliberative process, that is, the thinking of the Surgeon General, about whether to issue a new statement 2 in 1962? 3 A I am not specifically conversant with a 4 5 document that describes that. 6 Q Now, if we go back and take a look at 7 Dr. Burney's statement in 1959 in JAMA, are you familiar 8 with that statement? A I'm generally familiar with it. If you would 9 like me to discuss specifics of it, I would like to have 10 it in front of me. 11 Q Okay. I will do that, and I've actually 12 13 already highlighted it to tell you in advance what 14 particular parts of it I'm going to ask you about. 15 A Okay. 16 Q And I'd like to direct your attention, first of 17 all, to a statement that was made by Dr. Burney. It appears in his conclusions. And he has a conclusion 18 19 section, does he not? A If you would like me to describe the document, 20 21 it would be very helpful for me to have the document 22 where I can see it. 23 Q I'm going to give it to you in just a minute. 24 Do you recall he's got a conclusion session? page 296 page 297 1 If you would like me to describe the document, it is a very simple process to look at it. 2 3 MR. GRUENLOH: And again, this is what I 4 brought up before. This does impair the deposition, by 5 you not having extra copies of the document. 6 MR. BERNICK: Thank you, Counsel. 7 MR. GRUENLOH: No. You had time last night certainly to get extra copies of the document. 8 9 BY MR. BERNICK: 10 Q The conclusion section states, and I will give 11 it to you to read for your own, quote, "The Public 12 Health Service believes that the following statements

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are justified by studies to date: Number 1, the weight
13
    of evidence at present implicates smoking as the
14
    principal etiological factor in the increased incidence
15
16 of lung cancer." Do you see that statement as part of
17
    Dr. Burney's conclusion?
18
            I believe that you have read that correctly.
            Use of the word "implicates," was it reasonable
19
20
    for Dr. Burney to say that the weight of the evidence
21
    implicates smoking as a causative factor? Was that a
22 reasonable word for Dr. Burney to use in 1959?
23
    A I don't know what you're saying. It obviously
24 is a reasonable English language word. In the context
page 297
page 298
    of this sentence, it fits. It is traditional in
1
 2
    governmental language with lots of extra words contained
   in every statement. I mean, what is it that you're
 3
    asking me to offer an opinion on?
 4
 5
            MR. SCHROEDER: Mark that.
 6
    BY MR. BERNICK:
 7
     Q I just asked you whether that was a reasonable
    word for Dr. Burney to use in talking about the weight
 8
    of the evidence on causation?
9
        A In what context?
10
11
        Q In the context in which you wrote it in 1959,
12 as an official statement?
        A I believe that the statement is an appropriate
13
14 statement, including all of the words contained within
15 the statement, when viewed in context of the entire
16
   sentence.
17
         Q Are you aware of anyplace in the official
18 statement that Dr. Burney issued in the JAMA article in
19 1959 where Dr. Burney says smoking causes disease?
        A I believe that a reasonable English language
20
21 interpretation of the phrase, "The principal etiologic
22
   factor in the increased incidence of lung cancer" is a
23
     statement that cigarette smoking causes disease.
24
         Q That's your interpretation; correct?
page 298
page 299
         A That is my understanding of the English
1
2 language and scientific language that is expressed by
    those words, yes.
 3
 4
        Q It's true, is it not, that in 1964 the Surgeon
 5
   General made the statement, "smoking causes disease," in
 6
    just those words?
7
         A Yes, he did.
8
         Q Is there anywhere where you see in the
9 statement made by Dr. Burney in 1959 that simple
10 declaratory statement by Dr. Burney saying "smoking
    causes disease"? Is that anywhere in the document?
11
         A It is not in the document. There are good
12
13
    reasons why it's not in the document.
14
         Q Are you aware of anyplace prior to 1964 where
15
    the Surgeon General of the United States said in those
    simple terms "smoking causes disease"?
16
        A I am unaware of the Surgeon General using the
17
18
    word "cause" in a public statement as an official
    position of the Public Health Service prior to 1964. It
19
20
    is my understanding and opinion that the statement
21 contained in this volume, or in this paper, the
22
    "principal etiologic factor," is an appropriate
23
     scientific description that is intended to mean that
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24 cigarette smoking produced directly a rise in lung page 299 page 300 cancer. That is a statement of causation. MR. BERNICK: Move to strike as not responsive, 3 the last sentence. Q I'm asking a very simple question. I want to 4 5 know whether the statement that appeared in the 1964 6 report that smoking caused disease is a statement that 7 had been made by the Surgeon General in any context 8 prior to 1964? 9 MR. GRUENLOH: Objection; asked and answered. He answered it. He's entitled to explain his answer. 10 Go ahead and answer it again, Dr. Burns. 11 THE WITNESS: Okay. It is my opinion that this 12 13 statement in this page is a statement of causality. The word "cause," for reasons that are easily understood, 14 was not used by the Surgeon General prior to the 1964 15 16 report. 17 BY MR. BERNICK: 18 Q Do you --19 At least in an official position statement. Q Are you aware of anywhere where there is set 20 21 out in writing the reasons why Dr. Burney chose to use 22 the words that he did in his 1959 statement that we've 23 been talking about, which is that the weight of the 24 evidence implicates smoking as an etiologic factor? page 300 page 301 1 Α I'm not specifically conversant with whether Dr. Burney left a journal or other descriptions. And I 2. do not know of a specific document that described 3 4 his thoughts when he chose those specific words. Are you aware of anyplace prior to 1964 where 5 the National Cancer Institute issued a statement 6 7 publicly saying "cigarettes cause disease"? 8 A I'm not aware of the National Cancer Institute using the word "cause" in an official statement in the 9 context of tobacco and disease prior to 1964. 10 11 Q Let me ask you, Dr. Burns, if you would flip 12 through to see -- strike that. The American Cancer Society prior to 1964 said 13 "smoking causes disease"; correct? 14 15 A I believe that they said that following the 16 publication of their studies in 19 -- early 1950s. Mid 17 1950s. 18 The American -- strike that. 19 The American Public Health Association also 20 said prior to 1964 "smoking causes disease"; correct? 21 A I would not be surprised that that's true. I 22 don't have a specific recollection of a statement at 23 that point. 24 Q Do you know whether the Public Health Service page 301 page 302 generally and the Surgeon General in particular were 1 specifically asked to make the statement "smoking causes 3 disease" prior to 1964? A Without some context for that -- I'm certain 4 5 that somebody asked them. I don't know if -- they 6 probably got letters. They probably got all kinds of 7 things. I think you're asking for formal request by 8 someone.

9 Yeah. By Congress. 10 A I'm not specifically conversant with a formal request of the Surgeon General. I would not be 11 12 surprised that that happened. That was part of the ongoing political context at that time that led to the 13 14 need for the 1964 Surgeon General's report. 15 I don't have a specific recollection of a 16 specific document that describes a specific request 17 using the word "cause." 18 Q Let me just ask you a question, Dr. Burns, the 19 Public Health Service in general and the Surgeon General in particular are the -- is the highest health, public 20 health office in the United States; correct? 21 22 The Surgeon General is the chief officer of the U.S. Public Health Service. At the time that the 23 24 Surgeon General's report was released he was a chief page 302 page 303 officer over the administrative side of the agencies of the Public Health Service as well as the uniform branch of the U.S. Public Health Service. He was not the chief 3 health officer. That was the secretary of health and human health services, at that time the secretary of the 5 6 Department of Health, Education and Welfare. 7 The obligation of the Surgeon General of the 8 United States, the principal obligation of the Surgeon 9 General of the United States all the way up through 1964 was what? 10 The principal obligation of the Surgeon General 11 12 of the United States was the running and administration 13 and direction of the U.S. Public Health Service. Q I see. You don't think that the principal 14 15 obligation of the Surgeon General up to and as of 1964 was to protect the public health? 16 A That is the obligation of the Public Health 17 Service, among other obligations. The principal 18 19 obligation of that position is to run the organization 20 that does that. 21 Q Okay. Because the Surgeon General is supposed 22 to run the organization that does that, you don't think 23 that the Surgeon General has as his principal obligation 24 prior to 1964 to guard and watch over the public health? page 303 page 304 1 Α I mean, I don't want to engage in some kind of 2 semantic debate. Certainly --3 Neither do I. 4 Certainly the person running the organization 5 is committed to, obligated by, and intent on fulfilling 6 the missions of the organization. You asked me what the 7 position did, and I told you. 8 So we're in agreement that recognizing that the 9 Surgeon General was running the organization, that 10 because the principal obligation of that organization 11 was to guard and protect the public health, that was 12 also the obligation of the Surgeon General prior to '64; 13 correct? 14 Α Certainly. 15 Now, I think we talked about yesterday the fact 16 that by the early 1950s that smoking and health was a 17 major public health concern; correct? 18 A It certainly was. 19 Q And as a major public health concern, it

required a major public response; correct? 20 21 A Yes, it did. And certainly part of a responsible public 22 23 health activity and response was to tell the public in candid terms the nature and extent of the hazard posed 24 page 304 page 305 by cigarettes; correct? 1 2 A That is correct. 3 And part of telling the public about the nature 4 and extent of the hazard posed by cigarettes is being candid about whether smoking causes disease; correct? 5 A I don't know what you mean by candid. 6 7 Either --8 Being forthright about whether smoking causes 9 disease; correct? A That is correct. 10 11 Q Now, the Surgeon General of the United States, 12 charged with the responsibility of protecting the public 13 health --Yes. 14 Α 15 -- should certainly have said in simple terms, "smoking causes disease," if he believed, in fact, 16 17 smoking causes disease; would you agree with that? 18 A I think that you have an incomplete and, 19 perhaps, somewhat naive understanding of the way the 20 process of government works. The Surgeon General, as an individual, would 2.1 22 certainly be inclined to speak what he believed. The 2.3 Surgeon General, as the director of the Public Health 24 Service, is required, okay, in his official statements, page 305 page 306 to represent the Department of Health, Education and Welfare and the political administration of the president at that time. That constrains his or her 3 public statements on a variety of different issues. And oftentimes they do not have free rein to decide what 5 would be the best method for achieving that mission, 6 7 because other individuals at higher levels of government have other opinions about the priorities for the 8 9 executive branch of government, and have, being elected, the authority to exercise those priorities. 10 11 That creates an obligation on the part of the 12 Surgeon General to be direct and forthright. It also 13 requires that obligation to be fulfilled within a complex political construct that includes the secretary 14 15 of Department of Health, Education and Welfare, the 16 executive branch of government and the U.S. Congress. 17 Q Do you have any written evidence from any 18 source, Dr. Burns, that the Surgeon General's stated 19 views on the causation issue prior to 1964 were 20 constrained or limited in any fashion by political 21 considerations? 22 A As I sit here, from memory, without aid, I 23 don't have a specific recall of a specific document. My recollection is that there has been a variety of 24 page 306 page 307 1 documents written since that time and discussions with 2 the Surgeon General at that time, that indicate the 3 political pressure that was brought to bear with the production of the '64 Surgeon General's report. But I

don't have them in memory. I don't have them here with 5 me. And I don't have them by unaided recall as a 6 7 specific defined document. 8 Have you -- strike that. 9 Do you have any evidence that Dr. Burney 10 himself believed prior to 1964 that causation of disease by cigarettes had been proven? 11 12 A It is my understanding from reading the article that you have placed in front of me, that the English 13 14 language conclusion as the official position of the 15 Surgeon General, was one that states that the direct result of cigarette smoking was the increase in lung 16 17 cancer. Okay? While it is possible that Dr. Burney signed off on that recommendation without his believing 18 19 in it, I think that it is highly unlikely. So the only evidence that you really have of 20 21 Dr. Burney's views, his own personal views, are the 22 one -- is what he actually wrote in the JAMA article in 23 1959; is that fair? 24 A You asked me for evidence. I provided you with page 307 page 308 this piece of evidence. I'm assuming that there is also 1 2. evidence that exists. I don't have from unaided recall 3 a specific document or a specific reference to give you 4 that would define that. 5 MR. GRUENLOH: Do you need a break, Dr. Burns? THE WITNESS: I think it would be helpful, 6 7 sure. 8 MR. GRUENLOH: Before we break. In light of 9 the court's ruling yesterday, I understand why you're 10 plowing all of this old ground on causation and when the scientific community reached a consensus. But I really 11 think it is old ground, and I'm going to lodge an 12 objection as to scope here. If you want to take up all 13 your time in this deposition on old material, that's 14 15 fine. But it was my understanding that you were going to depose him, and I think you said this, on new 16 17 material and material that's related to this case, 18 specifically asbestos and synergy. 19 MR. BERNICK: If we would get a stipulation 20 from counsel that the only issue in this case is asbestos and synergy, I won't ask the witness any more 21 22 questions --23 MR. GRUENLOH: That's not what I said. I think 24 I refined what I said. page 308 page 309 1 MR. BERNICK: Excuse me, Counsel. I did not interrupt you. I'm not aware of any ruling that the 3 court made at this point that bears upon this 4 deposition. If there is some ruling that the court made 5 as to what we can cover in this deposition, I'm all 6 ears. But I'm not aware of anything like that. 7 These views, as I understand it, are directly 8 germane to what's in his report. So I'm going to ask him the questions, but --9 MR. GRUENLOH: Nevertheless, I will lodge an 10 11 objection as to scope. I think this is old ground, but 12 it's your time. 13 THE WITNESS: Let me make it clear that I'm 14 unwilling to conduct an interminable deposition today. 15 MR. GRUENLOH: Before we do take a break, I

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noticed that we were joined by another defense lawyer.
16
17
    If you could --
18
             MR. MOLSTER: My name is Charles Molster from
19
     Winston & Strawn on behalf of Philip Morris.
             MR. GRUENLOH: Thank you.
20
21
             MR. MOLSTER: Can I just have you tell me what
22
     ruling you're referring to?
23
             MR. GRUENLOH: It's my understanding that there
24
     was a ruling yesterday requiring the defendants, I think
page 309
page 310
1
    it was within 15 days, to respond to an interrogatory on
     causation. And I think that bears upon the issue that
 2
     Mr. Bernick is asking.
 3
 4
             MR. BERNICK: That's almost laughable. Could
 5
    you explain to me how that ruling has any bearing on
    this deposition?
 6
 7
             MR. GRUENLOH: Well, I also direct you to the
 8
    opening statements of the Engle trial. I don't know if
 9
    you've gotten a chance to read those yet, but I think
    they're directly contradictory to what you're trying to
10
11
    prove today. But the testimony will bear that out.
              MR. BERNICK: Let's go off the record.
12
              THE VIDEOGRAPHER: Off the record at 10:12 \text{ a.m.}
13
14
             (Recess.)
15
             THE VIDEOGRAPHER: We are back on the record at
16 10:24 a.m.
17 BY MR. BERNICK:
         Q Dr. Burns, at about the mid point of
18
19
    Dr. Burney's statement in 1959 on the causation issue he
20
    has a heading that says, "Criticism of the smoking
21
    hypothesis - not all investigators are in agreement with
22
     the conclusions reached by these researchers."
23
             Do you see that?
24
            I see that that is what is written, yes.
page 310
page 311
1
             In fact, it's true, is it not, that there were
     limitations on the scope of the epidemiological evidence
 2.
 3
     that had been gathered during the 1950s; correct?
         A I'm not quite sure what your question is
 4
 5
     intended to imply. The --
            Well, then I'll clarify.
 6
          Q
 7
             Okay, go ahead. That would be helpful.
          Q In the early 1950s, these epidemiological
 8
9
    studies came out linking smoking to disease. We've
     already talked about those; correct?
10
11
         A That's correct.
12
         Q And there were also mouse skin paintings that
13
    had been published; correct?
14
          A That's correct.
15
            All I'm asking is, the epidemiology that was
16
    available on the linkage of smoking and disease in the
17
    1950s, that was epidemiology that had some important
18
    limitations to it; correct?
19
            All epidemiology and all science has
20
     limitations. I'm not quite sure what you're intending
21
    to state. Certainly the evidence that has come out
22
     since that time has been more complete, has expanded
23
     information, has generated larger populations that were
24
     examined with a variety of other constraints, so that
page 311
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there was information available after that period that 1 was more complete, more detailed, more specific, over a 2. broader range of populations, etc. 3 4 But would you agree that the epidemiological studies that had been done prior to 1964 had not been 5 based on scientifically-designed samples and were, 6 7 therefore, subject to the criticisms that the findings 8 could not be generalized to the total population? I'm 9 reading from the '79 report. 10 A I think that that statement is technically 11 true. None of the epidemiologic studies, nor any epidemiologic study that I am familiar with, is truly a 12 representative sample by the nature of follow-up 13 required for an epidemiologic study or criteria for 14 15 selection for an epidemiologic study. And therefore, 16 they cannot be extrapolated to the U.S. population for 17 purposes of estimating the frequency of disease in that population. That is not the purpose for which those 18 19 studies were used in conjunction with defining the 20 relationship of smoking and disease. 21 Q I didn't ask you that. I just -- really all I 22 asked you was the question of whether the studies, the epidemiological studies that had come out prior to 1964, 23 24 had important limitations, given the way that they were page 312 page 313 1 designed as described in the '79 Surgeon General's report? 2. Well, I mean, I thought I answered both of 3 4 those questions. If I didn't, give me someplace where I 5 didn't clarify what I thought on those issues. 6 That sentence, you read correctly, I'm willing 7 to state that. 8 Q Out of the '79 report? 9 Out of the '79 report. You read it correctly. It is true that the epidemiologic studies -- and I'm 10 11 aware of no epidemiologic study that has follow-up that 12 is representative of the U.S. population. The purpose 13 of drawing a representative sample is so that you can 14 extrapolate the results, the percentage results to the 15 U.S. population. 16 Were --Q 17 That is a limitation for purposes of defining Α 18 the prevalence of disease in the U.S. It is not 19 necessarily a limitation for causal inference. 20 Q The views that Dr. Burney set forth in his 1959 21 statement on causation, those were views that other 22 scientists who had published in the area didn't agree 23 with; correct? 24 Dr. Burney cites several scientists who page 313 page 314 disagreed, that's correct. 1 2 Q In point of fact, if we go back to the early 3 1950s, there are a series of scientists -- I'm going to 4 go through a few of them. A series of scientists who issued articles or reports on the causation issue and 5 6 expressed the view that causation had not yet been 7 proven scientifically; correct? 8 A I believe -- maybe I misheard your statement. 9 But I think you're asking me whether they expressed the 10 opinion causation had not been proven? 11 That's right. Q

Okay. 12 13 Q Is that correct, those people had -- there were 14 people who issued articles and statements, scientists, 15 to that effect during the 1950s? A During the 1950s, and subsequently, there have 16 17 been a continued stream of individual articles who 18 adopted that position. 19 Q Okay. Now, if we go back to 1954, is it true 20 that in 1954 articles were published by Dr. Huber of the 21 National Cancer Institute on the question of smoking and 22 health? A I'm sure that Dr. Huber published articles in 23 24 the 1950s. page 314 page 315 1 Q Okay. 2 A If you would like me to comment on a specific 3 article, it would help me to be able to see the article that you're referring to. 5 Q Let me just ask you generally: Are you familiar with Dr. Huber's articles and publications 6 7 during the 1950s on smoking and health, generally? A I have a general understanding of Dr. Huber's 8 9 articles. I have not reviewed those in sufficient 10 detail to be able to cite them from memory, nor do I 11 have an encyclopedic recall of all of the articles that 12 he has published. Q Dr. Huber was with the National Cancer 13 14 Institute; correct? 15 A That's correct. 16 Q Do you remember what his position was within 17 the National Cancer Institute? 18 A I'm sure he held several different positions. 19 My recollection is that he was director of cancer 20 etiology and prevention, something like that. I'd have to go back and look at his title. 21 22 O Do you believe that Dr. Huber was qualified to 23 address the issue of whether smoking causes disease? 24 MR. GRUENLOH: Object to the form. page 315 page 316 THE WITNESS: I've not reviewed Dr. Huber's 1 specific qualifications in detail. I would assume that 2 3 given his position, that the Public Health Service felt 4 that he was qualified to offer an opinion. 5 BY MR. BERNICK: Q Okay. Are you aware of any business or 6 7 economic or other ties between Dr. Huber and the tobacco 8 industry during the 1950s? 9 A Not specifically, no. 10 Another person who spoke to the issue of 11 whether smoking has been proven as a cause of disease 12 was Dr. Hammond; correct? 13 A Cuyler Hammond, yes. 14 And certainly Dr. Cuyler Hammond was qualified 15 to address the issue of causation, was he not? 16 A Yes. 17 And Dr. Cuyler Hammond also issued fairly public statements setting forth his views on whether 18 19 causation had been demonstrated during the early 1950s; 20 correct? 21 A He has a number of statements throughout that 22 period on the relationship, yes.

```
And you're familiar -- I know that you've been
23
24 asked about this previously, but I want to set up a
page 316
page 317
    different question. You've been asked about statements
    that he made in the course of an interview that he gave
    with U.S. News and World Report in 1954. Do you recall
 3
            That's correct.
 5
         Α
 6
         Q And some of the questions or some of the
 7 statements that I know that you've been asked about
    include his statement that, quote, "We are undertaking
8
    the project," that is, a follow-up research project,
9
    "because there is reason to suspect that smoking may
10
11
    cause lung cancer - we don't know it, but there is good
12
    reason to suspect it."
13
            You're familiar with that statement that he
    made in 1954, are you not?
14
15 A Yes, I'm familiar with that statement. That
16 statement was in conjunction with the epidemiologic
17 research that he was about to publish at that point in
18
    time.
            And we're now talking February, 1954; correct?
19
20
         A I believe so. February 26th. That was
21 probably -- the interview may have been some days prior
22 to that.
            Was it unreasonable for Dr. Hammond to make the
23
    statement that I just quoted out of the U.S. News and
24
page 317
page 318
1 World Report? Was it unreasonable for him to make that
    statement at that time?
 2
 3
        A It was quite reasonable for him to make the
 4 statement that the scientific research he was about to
    publish had been undertaken as an epidemiologic research
 5
    project in order to establish whether or not cigarette
 6
 7
    smoking caused lung cancer.
8
         Q Dr. Wynder in February -- or April of 1954 also
9 issued a public article, published in the Connecticut
10 State Medical Journal. You're familiar with Dr. Winder,
11 are you not?
12
         A I am indeed.
            And Dr. Wynder was a -- one of the people who
13
14 authored one of those significant studies that came out
15
    in the early 1950s on smoking and health; correct?
16
         A That's correct.
17
         Q And he was with the Sloan Kettering Institute
18 for Cancer Research?
19
         A Yes, he was.
        Q And he was also qualified to address the
20
21 question of whether smoking caused disease; correct?
    A Yes.
22
23
         Q In April of 1954, he made the statement, quote,
24
    "The reasons for the apparent greater correlation of
page 318
page 319
    cigarette smoking with lung cancer are not entirely
 1
 2
 3
             Are you familiar with the statement that
 4 Dr. Wynder made at that time?
 5
        A Okay.
 6
         Q Do you have my question in mind?
 7
         A Perhaps you could rephrase it or reiterate it
```

8 for me. 9 Q Yeah. 10 A That it would be helpful. 11 Q The question that I asked you -- if you would give me the article back for just a second -- was 12 13 whether it was reasonable for Dr. Wynder to state in his article in April, 1954, that, quote, "The reasons for 14 15 the apparent greater correlation of cigarette smoking 16 with lung cancer are not entirely clear." Was it 17 reasonable for Dr. Wynder to make that statement in 18 1954, in April? 19 It was reasonable for Dr. Wynder to make that 20 statement in conjunction with his discussion of the 21 differences in lung cancer incidence between pipe and 22 cigar smokers. 23 Q You see that there's a further statement later 24 on about mouse skin painting? page 319 page 320 1 Α I do. Q And that basically Dr. Wynder in 1954 in that article talks about some of the limitations on the use of data from mouse skin painting. Do you see that? 4 A I see that. 5 6 Was it reasonable for him to make those 7 statements about the limitations on the use of mouse 8 skin painting data in April of 1954? A It was useful for him to make those statements. 9 I meant to say reasonable for him to make those 10 11 statements in 1954. 12 A It was reasonable to describe the -- his data 13 and the limitations of the interpretation of his data. 14 Both of those are reasonable things for him to have 15 16 Q As they appear on the article that you're 17 looking at, the April, '54 article? 18 A As they appear in the article where Dr. Wynder 19 concludes that cigarette smoking increases the risk of 20 lung cancer and he argues pervasively for prevention as 21 a major reason -- major approach to this problem. 22 Q He's not the only person who pointed out the 23 limitations of mouse skin painting, is he? 24 A He is not the only person who has done that. page 320 page 321 Q In fact, the American Medical Association 1 2 issued an editorial in the same year that talked about the limitations of mouse skin painting; correct? 4 A I am not certain that that is true. I would 5 not be surprised if that was a fact. 6 Q The American Medical Association was qualified 7 to issue statements regarding smoking and health in the 8 1950s, was it not? 9 It certainly had the opportunity to issue those 10 statements. And it had the resources to credibly review the information. 11 12 Q Okay. 13 MR. SCHROEDER: Will you mark that one for me? THE WITNESS: I mean, I can finish that answer 14 15 if it would make you happy. The issue is whether or not 16 the statements were actually based on a review or were 17 based on the role that the AMA was playing at that time, 18 which was a more political role in Washington in an

effort to alter the reimbursement for medical care. 19 20 And so it depends on -- they certainly had the potential. I've told you I didn't know the article you 21 22 were -- in question. I didn't know the statement in question. You asked me whether they were in a position 23 24 to do that. I told you that they had the potential to page 321 page 322 do it. Whether they actually did it would be dependent 1 2 on the context in which they did it, a scientific review, in which they certainly would be entitled to do it. Or a political statement. In which case it might 4 be driven by the political imperative. 5 MR. BERNICK: Could you read back the question 6 7 to the doctor, please? 8 (Record read.) 9 THE WITNESS: As I just described. I stand by 10 that answer. 11 BY MR. BERNICK: 12 Q I would just like to know whether they 13 qualified or not. Not whether they were politically 14 motivated, not whether they had the opportunity to. I'd just like to know whether the American Medical 15 16 Association was qualified to address the causation issue 17 in the 1950s? 18 A I think I answered that question fully. The 19 American Medical Association had the resources and 20 access to the expertise to review the information and 21 develop a credible position. It would be an expert 22 position on this issue. Q Now, the American Medical Association has 23 24 archives. They publish what's called the Archives of page 322 page 323 Industrial Hygiene and Occupational Medicine, or did in 1 the 1950s; correct? 3 A I don't have an encyclopedic recall of all of 4 their publications. I wouldn't be surprised if that 5 were true. 6 Q You what? 7 A I would not be surprised if that were true. 8 Q Now, you earlier described the process of review or expert review that takes place in connection 9 with editorials; that is, before an editorial is issued, 10 it has to undergo review by other experts. Do you 11 12 recall that? 13 A That's correct. 14 And you would certainly expect that the 15 American Medical Association would follow that same 16 process of expert review prior to issuing editorials; 17 correct? 18 In general that is true. The American Medical 19 Association also produces as editorial statements of the 20 American Medical Association. Those would be internally 21 developed and are usually not subject to external 22 review. But with that exception, they in general would 23 undergo review. 24 Are you familiar with the editorial that the page 323 page 324 American Medical Association issued in June of 1954? A Not by unaided recall without some prompting, 3 no.

```
I'm going to show you the editorial that was
 4
 5
     issued in June of 1984 by the American Medical
 6
    Association?
7
        A Are you sure you meant 1984?
8
         Q I'm sorry, 1954. Thank you. And ask you
    whether you're familiar with that?
9
        A I am generally familiar with it. I can't tell
10
11
    you that I have read it in detail.
12
         Q That was the official position of the American
13 Medical Association at the time? Or was this simply an
14 editorial by the two individuals who appear?
15
         A I'm not certain who Robert Eckardt and Philip
16 Drinker are, as to whether they are the officials of the
17
    American Medical Association or scientists who work in
18
    this area. It would appear as though it was an article
19
   that is developed by people asked to write the
20 editorial, but I can't be certain of that.
21
         Q There's nothing that purports to have that
22 editorial be an official statement of the American
23
    Medical Association; correct?
         A No, it here does not.
24
page 324
page 325
         Q So this is simply an editorial that appeared in
1
 2 the archives of the Industrial Hygiene and Occupational
 3 Medicine --
 4
        A Uh-huh.
         Q -- correct?
 5
            That's correct.
 6
         Α
         Q Directing your attention to the part of the
 7
8
   first paragraph that I bracketed, and I'll just read it
   into the record for a moment if you'll give that back.
9
10
            It says, "Various industrial dusts and fumes,
11 tobacco smoke and exhaust gases from heavy automotive
12 traffic have been suggested as possible factors in lung
    cancer. These materials have been tested chiefly on the
13
14
    skin of mice. However, the mere demonstration of
15
    materials in the air which are known to be carcinogenic
16 to mouse skin is not proof they cause cancer -- that
17 they can cause human lung cancer."
18
            Was that a reasonable statement for this
19 editorial to make in June of 1954?
20
        A That is a reasonable statement then. It is a
   reasonable statement now. The isolated demonstration of
21
22
    a single exposure in mice is not sufficient evidence to
23
    establish human carcinogenicity.
24
         Q Was it a reasonable statement for the editorial
page 325
page 326
    to make in 1954 that the factors that are listed,
1
    including tobacco smoke, were possible factors in lung
 3
    cancer? Is that a reasonable statement to make in June
 4
    of 1954?
 5
            The statement contained in this editorial is an
 6
    incomplete statement of the science that was available
 7
    at that time.
         Q I didn't ask you that. I asked you whether it
 8
9
    was a reasonable statement for the editor -- for the
    editorial to make in June of 1954 that --
10
11
         A My --
12
        Q Excuse me, that cigarette smoking was a
13 possible factor in the causation of lung cancer?
             MR. GRUENLOH: I think again you interrupted
14
```

Dr. Burns in the middle of his answer. So if you could 15 continue with your answer, Dr. Burns. 16 THE WITNESS: My understanding of the English 17 18 language use of the term "reasonable" includes whether 19 the statement was based on the evidence that was 20 available at that time. Okay? If I'm not responding to your definition of reasonable, then please let me know, 21 22 and I'll use some other definition. But is that your 23 understanding of the term "reasonable" as well? 24 BY MR. BERNICK: page 326 page 327 I'm just asking for your view on whether it was 1 2 reasonable for the editorial to state, as we have seen, 3 in June of 1954, that smoking was a possible factor in 4 lung cancer? 5 If you think it was reasonable, you say "yes." 6 If you don't think it was reasonable, you say "no." 7 MR. GRUENLOH: And Dr. Burns told you he had a 8 problem with the way that you were phrasing the question. I guess I need to object to the form of every 9 one of these questions if we're going to do this. But 10 he's telling you where he has the problem, what term 11 12 you're using that he as difficulty with. MR. BERNICK: That's a speaking objection. 13 14 It's inconsistent with the rules of practice in this 15 court. MR. GRUENLOH: Object to form. 16 MR. BERNICK: Thank you. 17 18 Answer the question, please. 19 My understanding of the term "reasonable" 20 includes whether or not the statement is based on the 21 facts that were available at that point in time. For the statement to be made that these materials have been 22 tested chiefly on the skin of mice is a statement that 23 is exclusively focused on the animal model testing of 24 page 327 page 328 carcinogenicity. It's quite widely accepted then and 1 2 now that animal model data in isolation of other data 3 are not sufficient to establish human carcinogenicity. 4 The statement, however, ignores the fact that at that time there was substantial data available that 5 6 established epidemiologically a relationship in humans. To ignore that data in making these statements, I think, 7 8 defines the statement as incomplete and not based on the 9 data that was available at that time, and therefore, not 10 reasonably reflective of all of the evidence that could 11 be brought to bear to answer this question. 12 Are you familiar with Dr. Robbins' textbook on 13 pathology? 14 A I'm generally familiar with that. 15 Q What is Dr. Robbins' textbook on pathology? 16 A It is a textbook on pathology. 17 Q Is it regarded as an authoritative source 18 within the field of pathology? 19 A It is a textbook. Textbooks are authoritative 20 only in the sense that the data contained within them are authoritative. The texts themselves are not 21 22 authoritative. Q Dr. Stanley Robbins, is he a person qualified 23 to speak to the issue in the 1950s as to whether smoking page 328

```
page 329
1 caused disease?
     A I don't know the specific qualifications of
    Dr. Robbins to address that issue.
 4
         Q Have you looked into that?
 5
         A I have not.
            Do you know whether Dr. Robbins, Dr. Stanley
 6
 7
    Robbins, who authored the textbook of Pathology, had any
8
    ties to tobacco?
         A I'm not familiar with whether Dr. Robbins did
9
10 or did not have ties to the tobacco industry.
         Q Dr. Milton Rosenblatt, are you familiar with
11
12 his publication on cancer of the lung in the 1950s?
         A Not by unaided recall, no.
13
            Do you remember anything about Dr. Rosenblatt?
14
15
         A I would need more prompting than that for an
16 isolated name. I don't generally store information by
17 individual names.
18
         Q Associate of professor of medicine, New York
19 Medical College; visiting physician and chief of Chest
20 Clinic, New York City Hospital; fellow of the American
21
    College of Chest Physicians; American College of
    Cardiology; New York Academy of Medicine; American
22
23 Medical Association.
24
         A So he was --
page 329
page 330
         Q Author of Cancer of the Lung, Pathology,
1
    Diagnosis and Treatment, published by Oxford University
 3
    Press, 1956. Ring any bells?
 4
         A Not specifically, no.
         Q The Burney statement itself in 1959 in JAMA,
 5
 6
    there was a response to that, was there not?
7
         A I'm assuming that there was, yes.
            Well, in point in fact, the editors of the
8
9
    Journal of the American Medical Association made a
10
    response to the Burney statement almost immediately
    after it was issued; correct?
11
12
         A I don't have a specific recall of that.
13
         Q Well, what is the practice when an editor
14 responds to an article that appears in the journal? How
does that editorial get put together?
16
         A In that setting, it is usually an editorial
17
    written by the editor. Sometimes the editor will submit
18
    that for external review. Oftentimes they do not.
19
         Q The editors of the Journal of the American
20 Medical Association in 1959, when Burney issued his
21 statement, were they qualified to address the issue of
22
    whether smoking caused disease?
         A I don't know. They certainly had expertise
23
24
     available to them that they could draw on. Whether they
page 330
page 331
1
    as individuals were qualified to do that or not would be
    a matter of individual qualification. And I'm not
    familiar with their individual qualifications.
 3
         Q Are you aware of any ties between the tobacco
 4
    industry and the editors of the Journal of the American
 5
    Medical Association in 1959?
 6
 7
         A Not as individuals. Certainly the American
 8 Medical Association had substantive ties to tobacco
 9 throughout that period and subsequently.
10
         Q On December 12 of 1959 -- the date of the
```

Burney article itself was what? I think you have it in 11 12 front of you there. 13 A I believe it is -- let me check the next page. 14 November 28th, perhaps, 1959. Q Okay. I want to put before you the Journal of 15 16 the American Medical Association, December 12th, 1959, and ask you whether this contains the response of the 17 18 editor of the Journal of the American Medical 19 Association to Dr. Burney's statement earlier in the 20 year? 21 I believe that that's a response to the 22 information, yes. Q Basically the editor of the journal was issuing 2.3 24 a response to what Burney had said in the statement that page 331 page 332 1 he made in 1959 in JAMA; correct? A He was simply describing the context that he 3 felt that statement fit. 4 Q Okay. And if you'd hand that back to me for a 5 moment. The editor says, in part, "That a number of 6 authorities who have examined the same evidence cited by 7 8 Dr. Burney do not agree with his conclusions." Was that a reasonable statement for the editor of JAMA to make in 9 10 1959? That was a reasonable statement for the editor 11 to make. It was the same statement that Dr. Burney made 12 13 in his own article. 14 Q He goes on to say, "Although studies reveal a 15 relationship between smoking and cancer that seems more than coincidental, they don't explain why even when 16 17 smoking patterns are the same, case rates are higher among men than among women, and among urban rather than 18 19 among rural populations." 20 Was that a reasonable statement for the editor 21 of JAMA to make in December of 1959? A That was a statement that was reasonable at 22 23 that point in time. And it is a statement that is 24 intended to predicate the following statements, which is page 332 page 333 that you can't make an all-or-none statement, which is 1 that all of lung cancer is caused by cigarette smoking. 3 And no one has made that statement at any point in time 4 that I'm aware. Q And then it goes on to say, quote, "Until 5 definitive studies are forthcoming, the physician can 6 7 fulfill his responsibilities by watching the situation closely, keeping current of the facts, and advising his 8 9 patients on the basis of his appraisal of those facts." 10 Would you agree that that's a reasonable 11 statement for the JAMA editor to make in the December of 12 13 I think that that is a general admonition that 14 would apply to all aspects of science and medicine then 15 and now. 16 Q I'm just asking whether it was a reasonable statement for the editor to make in 1959? 17 18 A If it was reasonable then and now, is that not 19 an answer to your question? 20 Q Can you just answer the question, Dr. Burns? 21 Was that a reasonable statement for the editor to make

in JAMA in December of 1959? 22 23 A I think it a reasonable admonition for the 24 editor of a journal to make to its readership of page 333 page 334 scientists and physicians at that time and currently. 1 Q Now, it was not only the editor of JAMA who 3 responded to Dr. Burney's 1959 statement? There were 4 others who also responded; correct? 5 A I mean, I don't know how to answer your 6 question. Obviously the tobacco industry responded. 7 There were other individual scientists who responded. There were probably other organizations who responded. 8 9 Q I'll be more specific. One of the other people 10 who responded, one of the other scientists who responded 11 to Dr. Burney's 1959 statement was Dr. Berkson 12 (phonetic); correct? 13 A Dr. Berkson responded on repetitive occasions 14 to the -- anyone's statement that cigarette smoking 15 caused disease. 16 Q In fact, he wrote his own letter to the editor, 17 which appeared in the subsequent addition of the Journal 18 of the American Medical Association; correct? 19 A It would not surprise me in the least that 20 Dr. Berkson did that at that point in time as he has 21 done it at multiple occasions since that time as well. 22 O Dr. Berkson was with the Mayo Clinic; true? A I don't know specifically where he was located 23 24 at that time. page 334 page 335 Q Have you looked into what his qualifications 1 were to address the issue of whether smoking caused 3 disease in the 1950s? A I cannot cite without unaided recall 4 Dr. Berkson's qualifications. My understanding is that 5 he was a statistician scientist who was interested in 6 7 the topic. 8 Q Well, he was also a medical doctor, was he not? 9 A My understanding was that his criticisms were 10 largely in the area of statistics. He may have well 11 been an M.D. As I said, I don't have a specific knowledge of his CV. 12 13 Q Do you know whether he was qualified to address 14 the question of whether smoking caused disease in 1959 15 and 1960? A I have not conducted a specific review of 16 17 Dr. Berkson's qualifications for purposes of defining 18 whether or not he was qualified. I have read several of 19 his articles over time describing his concerns about the 20 establishment of a causal relationship between smoking and health. 22 Q Are you aware of any ties that Dr. Berkson had 23 to the tobacco industry? 24 A I'm not specifically conversant with his page 335 page 336 1 financial arrangements and whether or not he had any 2 ties to the tobacco company. 3 Q Are you familiar with Dr. Louis Robbins of the 4 cancer control program of the Public Health Service who 5 wrote on the issue of smoking and health in 1962? 6 A I'm generally familiar with Dr. Robbins.

```
Dr. Robbins was as, I indicated, chief of the
     cancer control program at the Public Health Service in
 8
9
     the 1960s; correct?
10
        A I'm willing to accept your attestation that
11
     that was true.
12
            Well, certainly Dr. Louis Robbins was a person
13
     who was qualified to address the issue of smoking and
14
     disease in the early 1960s, was he not?
15
          A I have not conducted a detailed review of
16
    Dr. Robbins' background and CV. Certainly one would
17
    expect from his position at the public health, that the
    U.S. Public Health Service felt that he was qualified.
18
            You're not aware of any ties between
19
20
    Dr. Robbins and the tobacco industry, are you?
21
         A No, I'm not.
             And it was the view of Dr. Robbins as of 1962
22
    that a distinction had to be made in looking at the
23
     causation issue between the perspective of the medical
24
page 336
page 337
     investigator and the perspective of the medical
1
     practitioner; do you recall that?
          A \,\, I recall that article. That was the reason --
 3
 4
     it's my understanding that that was the reason why
 5
    Dr. Burney chose to express the relationship between
 6
     smoking and disease in the terms that he used rather
 7
    than to enter into the fray about whether the term
     "cause" should be restricted for experimental proof as
 8
    opposed to the general understanding use of that term
9
10
    where one event results in another.
11
          Q It was the perspective of Dr. Robbins that
12
    unless you were able to demonstrate experimentally that
13
    cigarettes caused disease from the perspective of a
14
    medical investigator, you couldn't say cigarettes caused
    disease; correct?
15
          A I think that's a mischaracterization of what he
16
17
    said. What he was saying was that for purposes of
    dealing with the issue of taking care of people, of
18
19
    preventing the disease, that the evidence was sufficient
20
    to be able -- the evidence that existed was sufficient
21
    to be able to say that smoking caused disease and that
     people should not smoke, and that that would prevent
22
     disease.
23
24
             For purposes of narrowed philosophical use of
page 337
page 338
    the term "causation" as it is used by experimental
1
     scientists, that term, if one chooses to restrict it to
 3
     pure experimental truth, would require experimental
 4
     proof of causation prior to the use of that term.
 5
              I think he was drawing that distinction because
 6
     it was a common philosophical debate at that time --
 7
          Q In --
 8
             -- particularly in relation to use of
 9
     epidemiologic data as to whether or not causation as a
     term should be reserved for a purely experimental proof
10
     or a derivative proof, as in mathematics, or whether
11
12
     causation could be used in the general English use of
13
     that term, which was that one exposure or one event
14
    directly results in another.
15
         Q
            When you say "at that time," you're talking
16
     about 1962?
17
         A I'm talking about what he is expressing in his
```

18 article at that time, yes. 19 Q And he states in the article, quote -- this is 20 Dr. Robbins stating in his 1962 article, quote, "For the 21 medical investigator, however, the evidence still does not add up to conclusive proof that cigarette smoking 22 23 causes lung cancer." Right? What he says, very clearly, in his article, is 24 page 338 page 339 that there are two positions. Okay? One is for 1 2 purposes of public health, for purposes of dealing with individuals, for purposes of preventing disease. And 3 the other is as a medical investigator for purposes of 4 experimental proof, in a purely experimental scientific 5 6 context. 7 What he says is that within the public health 8 context, for purposes of dealing with people, that the 9 conclusion is legitimate that cigarette smoking causes 10 disease, and that that has been established. What he 11 also says is that the pure experimental proof which requires an exploration of the mechanisms of disease 12 13 occurrence and development of all of those chain of 14 events has not been completed. 15 Q In that context, Dr. Burns, was it reasonable 16 for Dr. Robbins to state in 1962, quote, "For the 17 medical investigator, however, the evidence still does not add up to conclusive proof that cigarettes smoke 18 19 causes lung cancer"? A I believe I've defined what he said in the 20 21 article in the appropriate context. I'd be happy to do 22 that again. But I believe that that was -- is an 23 appropriate discussion in the context as I defined it. 24 Q Dr. Burns, you yourself have drawn a page 339 page 340 distinction between proof of causation -- strike that. 1 Between answering the question of whether cigarettes cause disease for purposes of scientific proof and 3 answering the question of whether cigarettes cause 4 5 disease for purposes of taking action; right? correct that you yourself have drawn that distinction? 6 7 A I'm not quite sure what you're referring to. I 8 certainly have, indeed, at various points in time 9 expressed my opinion on causation. 10 Q Well, you testified specifically in the fall of 11 1998 that there was a difference between scientific 12 proof which would meet the epidemiological standards, 13 and enough of a showing of relationship between smoking 14 and disease to take action; correct? A I believe that that is correct, that there are 15 16 multiple stages. There is a stage at which the evidence 17 is sufficient to be concerned. There is a stage at 18 which the evidence is sufficient to take action. And 19 then there is a stage at which scientific proof has been 20 established. 21 At what point in time do you believe that there 22 was sufficient scientific proof of causation for a 23 warning to be issued to the general public that 24 cigarettes may cause disease? page 340 page 341 A Okay. It is my understanding that the issues of warning are legal issues. And I would not want to

offer an opinion about the legal basis, okay, for 3 4 requiring a warning. I believe that by 1950, or the early 1950s, 5 6 individuals who were knowledgeable about the science that existed at that time were entitled to a reasonable, 7 direct, and appropriate concern that it was likely that 8 cigarette smoking caused lung cancer. 9 10 I think that by the mid 1950s, that reasonable 11 people would be expected to draw a conclusion that 12 cigarette smoking probably caused lung cancer, and that 13 actions should be taken. And then certainly by the time of the '64 report, and more likely by the time of 14 Dr. Burney's statement, the mid to late 1950s, the 15 conclusion that this was a scientific fact, okay, was 16 17 indeed one that I believe scientifically was the 18 appropriate conclusion. All of those should translate into warnings, as 19 is appropriate under the law and precedent that exists. 20 21 And I'm not knowledgeable in that enough to offer an 22 opinion as to what specifically would be required. But medically and scientifically I have defined what I think 23 24 the science would support at those points in time. page 341 page 342 1 And just so we're clear, you aren't aware of any statement by Dr. Burney prior to December of 1959; 3 correct? I mean, we have covered this in -- on multiple 4 occasions. That is the first official statement. I'm 5 6 certain that Dr. Burney spoke and, perhaps, wrote on 7 this in a less formal and less official context. That is the first official statement by Dr. Burney for the 8 9 Public Health Service. Q Could you identify for us any prior statement 10 where he sets out a position of the Public Health 11 Service on the issue, prior to 1959? 12 13 A I have told you that this is the first 14 statement, official statement of the Public Health 15 Service by Dr. Burney on this issue. 16 O Now --17 A That I am aware of anyway. Q Now, we've had a lot of discussion about when 18 19 there was a consensus of the scientific community on 20 whether smoking caused disease; true? 21 A I think there's a fair statement that that has 22 absorbed a bulk of our time, that's correct. 23 And I take it you would agree with me that the 24 fact that there is a scientific consensus does not mean page 342 page 343 that there are no people who have different views on the 1 2 subject? 3 That is correct. 4 Q And certainly when it comes to the issue of 5 whether causation had been proven scientifically, there were a number of scientists throughout the 1950s, and 6 7 indeed, in the early 1960s, who felt that it had not 8 been scientifically proven that cigarettes caused 9 disease; correct? 10 There were individuals at that time who held 11 that position. There are individuals now who hold that 12 position. They are indeed a dwindling few. But there 13 are individuals even currently who hold that position.

Well, I want to focus on the period of time 14 15 prior to 1964. 16 A Okay. 17 Q Would I be correct in saying that there were qualified scientists who had no ties to the tobacco 18 19 industry who felt and published the view prior to 1964 that the causation of disease by smoking had not been 20 21 scientifically proven? 22 MR. GRUENLOH: Objection to form. 23 THE WITNESS: As we have already demonstrated 24 here with an individual that I agree had qualifications, page 343 page 344 who wrote an article in that time period, okay, that 1 individuals expressed that opinion. Most individuals 2 3 who expressed that opinion differentiated between the 4 use of causality in a pure experimental scientific context, as opposed to the general English language use 5 of the term, and therefore, were drawing that 6 7 distinction, saying that the laboratory evidence was not sufficient to build fully the mechanistic causal link 8 9 that established the relationship between exposure to the ultimate occurrence of disease. 10 11 That statement, okay, was true, then; it is 12 true now. There are individuals who hold that position 13 then; there are individuals who hold that position now. 14 Okay? There were also individuals who felt --Dr. Burney, this is -- you are going on and 15 16 this is not responsive to my questioning. I asked you a 17 simple question. 18 A I'm very flattered, but I am not Dr. Burney. 19 Dr. Burney was a distinguished Surgeon General. I'm 20 just a professor of medicine. 21 Q I think you get my drift. Should I put the 22 question to you again? 23 I think you are interrupting my question --24 I was interrupting your answer because you were page 344 page 345 1 going on. It wasn't responsive. MR. SCHROEDER: Would you mark that? THE WITNESS: I was trying to be responsive to 3 4 your question. MR. GRUENLOH: Please do mark that. That was a 5 perfect example of you talking over the witness. If you 6 7 have a problem with his answer, define your question better. Object to form. 8 9 BY MR. BERNICK: 10 Q I'll put the question to you. Isn't it a fact 11 that prior to 1964 there were qualified scientists with 12 no ties to the tobacco industry who published the view 13 that it had not been scientifically proven that 14 cigarettes caused disease? 15 A In view of the extensive discussion we have 16 just had of one of the papers of a scientist who did 17 that, I think that the answer to the question is that, of course, there were scientists who did that. Most of 18 the scientists, as I said, distinguished between 19 20 experimental proof, which was what your question, as I 21 understood it, to be directed at, from the English language use of that term "causality," whether or not 22 23 the events or exposure directly resulted in the 24 occurrence of the illness.

page 345 page 346 1 Q How many such scientists were there? A I don't have a count. Do you know of anybody -- strike that. 3 4 Do you know of anybody who wrote during this 5 period of time that those scientists who expressed this 6 view, that is, that causation had not been demonstrated, 7 were not acting in good faith? 8 A I know of no one who wrote that. I would not 9 mean to imply that. I think that they were using a different set of standards for the philosophical use of 10 the term "cause" within the scientific context, and they 11 12 wanted to reserve that term for experimental proof. 13 Q Do you believe that their perspective was an 14 unreasonable scientific perspective? A I think that --15 16 At the time? 17 A I think that it is a philosophical perspective 18 about the use of the term. I don't believe that it would be reasonable for individuals as scientists to 19 20 hold that we need a complete and total description of the entire biologic basis for the occurrence of disease 21 22 before we have the knowledge to conclude that the 23 disease is produced by a specific agent; and therefore, 24 I think that if that is the standard and that is the page 346 page 347 1 standard that some were trying to apply, that is 2 unreasonable. 3 If one is adopting a standard that there needs to be some understanding of the basic mechanism by which 4 5 an exposure could result in the disease in question, I think that's quite a reasonable standard. 6 7 Q And that's certainly the perspective that was being articulated by Dr. Robbins in 1962; correct? 8 9 A I've outlined several perspectives. Which one are you referring to? 10 11 Q The last one, that there had to be some 12 reasonable demonstration experimentally. 13 A No. Dr. Robbins said that the evidence for the general understanding, English language use of the term 14 "cause," okay, for purposes of public health, for 15 purposes of Dr. Burney's statement for public health, 16 17 that the evidence was sufficient to draw a direct 18 relationship. 19 He was saying, however, that the mechanistic 20 understanding with experimental demonstration in the 21 laboratory had not been completed. 22 Q I'll be more precise. The perspective that is 23 described by Dr. Robbins in 1962 as the perspective of 24 the medical investigator, was that or was that not a page 347 page 348 reasonable perspective in 1962? Reasonable for what purpose? 2 Reasonable for scientific purposes; that is, to 3 4 be able to say for scientific purposes that causation 5 has been demonstrated? 6 A It is certainly true that if one applies 7 circular logic to that statement, which as I understand 8 it is what your question is doing, that it is certainly true. That it is a reasonable thing for a scientist to

do to hold a standard and to expect that that standard 10 11 would be met. 12 If you are asking me whether it is a reasonable 13 for a scientist to hold that that experimental process needs to be complete, and that experimental use of the 14 15 term "causality" needs to be complete before action is taken, before a statement of causality for purposes of 16 17 public health is taken, okay, then I don't believe that that's reasonable, and I also don't believe that that is 18 19 the position that was articulated by Dr. Robbins. 20 Q Okay. Do you believe that the medical 21 investigator, the perspective of the medical investigator described by Dr. Robbins in 1962 was a 2.2 23 reasonable perspective as he described it at that time? 24 A I am frankly at a loss as to what I have not page 348 page 349 communicated on this issue to you. I think that 1 Dr. Robbins' position --3 Q I didn't ask you that Dr. Burns. I'll try to 4 be clearer. A Okay. I don't understand your question. I'm 5 sorry. 6 7 Dr. Robbins describes the perspective of the 8 medical investigator; correct? 9 A He describes the perspective of the medical 10 investigator with a specific use of that philosophical approach to mean the restriction of the proof of 11 scientific causality to experimental proof in the 12 13 laboratory. 14 All I'm asking is, was the perspective of the 15 medical investigator, as described by Robbins in 1962, 16 was that a reasonable perspective? A It is reasonable perspective for a scientist 17 working in an experimental context to continue to work 18 19 in that context to develop a full understanding of the 20 causal chain of events between something that is known 21 to cause a disease and the subsequent occurrence of that 22 cause of disease; that indeed, is a very clear and very 23 reasonable action on the part of an investigator. 24 It is also reasonable, as Dr. Robbins page 349 page 350 1 articulates, to say that for purposes of public health, 2 we can define this causal relationship while we are in 3 process of examining experimentally the precise mechanism by which that process has occurred. And he 4 5 acknowledges that many people would reserve the term 6 "cause" until that experimental demonstration has 7 occurred. All of that is something that I would find to 8 be reasonable. 9 Dr. Burns, you've talked to -- strike that. 10 You've made mention, I believe, in your -- I'll 11 tell you what -- strike that. 12 Let me try to get one more thing, and then 13 we'll change tapes. 14 Are you familiar with Dr. Clarence Cook-Little? I am -- I know who he is. I've never met him. 15 Did Dr. Clarence Cook-Little act as the 16 17 scientific director for the organization called the 18 Tobacco Industry Research Committee? 19 A I believe that he did. I'm not -- I thought it 20 was council, but it may have been committee.

```
Q And he issued a series of statements in the
21
22 1950s on behalf of that organization regarding smoking
23
    and health, did he not?
24
        A He did.
page 350
page 351
         Q And in order to set out his views clearly, he
1
    actually published an article in Atlantic Magazine
 3
    in 1957; correct?
 4
         A I'm not specifically conversant with that
 5
    article.
         Q It was the view of Dr. Little throughout the
 6
 7
    1950s that the causation of disease by smoking had not
    been scientifically demonstrated; correct?
 8
9
         A I believe that that was Dr. Little's opinion
10
    throughout his entire tour of association with the
    Tobacco Research Council.
11
12
         Q Now, isn't it also true that when Dr. Little
13 expressed that position he did so expressing the
14
    position and views of the scientific advisory board of
15
    that same organization?
16
         A I am not sure that that was true.
17
         Q Did you take a look to see whether the articles
18 when published specifically cited that the views were
19
    approved by the SAB?
20
         A I did not specifically review that. I'm aware
21 that subsequently that process was not followed. I
    don't know specifically what statement was approved or
2.2
    how it was referred to. If you could help me with that,
23
24
     I could offer more reasoned opinion.
page 351
page 352
1
            Yes, I'll show you the -- see if you can
    refresh your recollection. I'll show you Exhibit -- the
    article out of the Atlantic in December of 1957, which
 3
    you'll see is by Dr. Little on the specific issue of
 5
    whether he's stating simply his own position or also the
 6
    position of the Scientific Advisory Board. You may want
 7
    to take a look at page 76 and the paragraph immediately
 8 over the heading, quote, "The right to learn and to
 9 inform."
         A I'm not sure where I'm supposed to be looking
10
11 here.
12
         Q Just above the --
13
         Α
            This page? Page 76? 75?
14
         Q Yes.
15
         A I was reading page 75. I'm sorry.
16
             He notes in his article, I quess in the
17 Atlantic Monthly, "It is important for the public to
18 remember that members of the Scientific Advisory Board
19
    in their approach to this research responsibility take
20
    the position that smoking has not been proven guilty or
21 guiltless in matters affecting human health." Since --
22
            Do you want to finish what he says is their
23
    view?
24
             I'd be happy to. "Their attitude is that
page 352
page 353
    statistical and indirect evidence does not prove its
1
 2 guilt as a causative agent. The open question of its
 3 innocence or its guilt can best be answered through
 4 unhampered scientific research for the full facts."
 5
         Q Are you aware --
```

The science advisory board at this time was set 6 7 up in response to the Frank statement, where the Frank statement by the tobacco industry said, "The evidence 8 9 has not established that smoking causes any disease." It would not be surprising that individuals who signed 10 11 on to the Scientific Advisory Board would be willing to 12 accept that position by the tobacco companies. 13 What he says in his article, however, is that the Science Advisory Board for the purposes of examining 14 15 the basic science has adopted the position that there is neither proof nor lack of proof. That is the basis of 16 any scientific investigation. You don't enter into a 17 scientific investigation if you know the results 18 already. That is not a statement that the Science 19 20 Advisory Board endorsed Dr. Little's positions then or 21 in perpetuity on whether or not it was reasonable for 22 purposes of public health to decide that there was a 23 causal relationship between smoking and disease. MR. SCHROEDER: She's got to change the tape. page 353 page 354 THE VIDEOGRAPHER: We're going off the record 1 2 at 11:24 am. 3 (Recess.) 4 THE VIDEOGRAPHER: This marks the beginning of 5 Videotape Number 2 of Volume 2 in the deposition of Dr. David Burns. We are back on the record at 6 7 11:29 a.m. BY MR. BERNICK: 8 9 Q Dr. Burns, are you aware of any evidence that 10 anybody from the SAB ever stated or suggested prior to 1964 that Dr. Little had misrepresented their views? 11 12 A I don't believe that that statement was made, 13 Q Okay. If we focus on this period of time that 14 15 is prior to 1964, are you aware of any evidence that any 16 of the views expressed by the tobacco industry on 17 causation of disease had been acted on by any doctor for 18 any medical association? 19 A That question is so broad that it cannot 20 possibly be answered. 21 Q Okay. Well, let me break it down. 22 A Okay. 23 Are you aware of any doctor or medical 24 association prior to 1964 who ever recited the views of page 354 page 355 the tobacco industry on the causation issue and said 2 that he or they agreed with those views? 3 A From unaided recall, I can't produce from 4 memory a specific document that includes all of those 5 pieces in it. It certainly was commonly true at that 6 time that individuals such as Dr. Berkson reiterated the 7 same arguments that were being made by the tobacco 8 companies and placed them in the context of a denial of 9 the establishment of scientific causality. 10 I am uncertain as to whether any of those 11 articles actually discussed the tobacco industry's position as part of the basis of forming the body of 12 13 evidence. But the evidence being cited by those individuals was essentially the same as the positions 14 15 adopted by the tobacco industry. 16 I am also aware, but don't have from unaided

recall, that many of the professional organizations 17 18 adopted positions consistent with those of the tobacco companies, and that those positions were influenced by 19 20 tobacco industry positions even though that influence 21 was not acknowledged directly in the position 22 statements. 23 Q Are you aware of any actual evidence that the 24 positions taken by any doctor or medical association on page 355 page 356 causation was, in fact, influenced by statements made by 1 the industry on that question? A While I don't have a specific document in front 3 of me or available by unaided recall, it is my 4 5 understanding that there was a substantial interaction 6 between the U.S. tobacco companies and the American 7 Medical Association during and subsequent to the 1964 period, that is construed by many, including myself, to 8 9 have influenced their positions. 10 Q I'm talking about before 1964. Are you aware of any actual evidence that the views of any doctor or 11 12 any medical association were influenced by statements made by the tobacco industry concerning the causation 13 14 issue? 15 My understanding is that that relationship with 16 the AMA antedated the 1964 period. I don't have a 17 specific document that I can recall from memory that 18 establishes that to be true. Q Are you aware, is there any such document that 19 20 appears in your report or in any of your reliance 21 materials? 22 A I did not address that specific issue in either 23 my report or my reliance materials. Q Are you aware of any actual evidence that any 24 page 356 page 357 doctor, medical association, or public health authority acted, that is, took action, on the basis of the 2 industry's views about causation prior to 1964? 3 4 A It is my understanding from discussions with 5 people who were involved at that time that the position taken by Dr. -- taken for the development of the 1964 6 7 Surgeon General's report was a substantive response to 8 the articulated position of the tobacco companies that 9 smoking causation had not been established, and that 10 that was an action that was taken directly in response 11 to the tobacco industry's statements and their political 12 influence to implement those statements in the U.S. 13 Congress, and that that was the purpose for conducting 14 such an extensive and elaborate process to examine this 15 issue in 1964. 16 Q Do you have any actual documentary evidence of 17 that? 18 As we sit here with unaided recall, I don't 19 have a specific document. I have discussed that with 20 people who were participants at that time, but I don't have a specific document that I can point to as we sit 21 22 here with unaided recall. 23 Q Well, is it anywhere in your report or your 24 reliance materials? page 357 page 358 1 A I did not address that specific issue in the

reliance materials or in the report. 2 Q Apart from what you say is the action 3 undertaken to basically produce the '64 Surgeon 4 General's report, are you aware of any actual evidence that any doctor, medical association or public health 6 7 authority took action on the basis of the industry's views about causation prior to 1964? 8 9 A It is my understanding, and I don't have the document in front of me, and can't recall it with 10 11 unaided -- from unaided memory, that the positions of 12 the American College of Chest Physicians, among others, 13 were influenced by the positions of the tobacco companies, as expressed by representatives from those 14 states that -- where tobacco was a major crop in the 15 formation of those opinions. I don't have a specific 16 17 document that describes that deliberation, nor a specific document that defines that influence. 18 19 Are you aware of any public health authority 20 who took any action based upon the industry's expressed 21 views about causation prior to '64 other than what you say is the action that was taken to produce the 1964 22 23 Surgeon General's report? 24 A What action are you asking me to -page 358 page 359 1 Any kind of action at all. Are you aware of any actual evidence that any public health authority 2 took action prior to 1964 based upon the industry's 3 expressed views about causation? 4 5 A You're asking for an action that they took 6 based on the absence of an effect? I mean --7 Q No, I'll rephrase the question again. 8 don't -- I want to avoid a long dialog about this. asking you for something that I think is relatively 9 10 simple. The industry expressed its views, that is, the 11 12 tobacco industry expressed its views about causation 13 prior to 1964; correct? 14 A Yes. 15 All I'm asking is, are you aware of any action 16 that public health authorities either took or failed to 17 take prior to 1964 as a result of their relying upon the views expressed by the tobacco industry on the causation 18 19 issue? 20 Okay. It is my understanding that the U.S. 21 Public Health Service and various other agencies took some actions to deal with the tobacco issue prior to 22 23 1964. The extent and effectiveness and magnitude of 24 those actions, it is my opinion, was substantially page 359 page 360 influenced by the fact that there was an ongoing 1 political debate directed and orchestrated by the 2 3 tobacco industry as to whether or not the science had established causality. That interfered with delivery of 5 public messages and effective public action on the part 6 of various agencies. 7 I don't have a specific document in mind that 8 establishes that that influence interfered directly with 9 a specific action. Q The 1964 report clearly was a landmark report; 10 11 correct? A It was an important document. 12

```
Well, the Surgeon General in 1989 called the
13
14
    '64 report a landmark event; correct?
15
         A He did.
16
         Q And you'd agree with that statement; correct?
17
         A I have no reason to disagree with that
18
     statement in the context in which he used it.
19
         Q The 1989 Surgeon General's report also talks
20
     about the impact of the 1964 report, does it not?
21
         A I'm certain it does, yes.
22
            In fact, in 1989, the Surgeon General describes
23
     the mobilization of resources to deal with smoking and
    health and basically get people to quit smoking; right?
page 360
page 361
1
            Yes. Following the production of that report,
 2
     and its conclusion, there was a substantially greater
     effort on the part of the voluntary health agencies and
 3
     others to deal with the public health problem defined by
 4
 5
     the Surgeon General's report.
 6
         Q In fact, in the 1989 report, -- which was the
 7
     20th Surgeon General's report; correct?
8
         A I'm perfectly willing to accept that number.
9
            It describes the fact that there has been
10
     "dramatic progress that has been achieved in the past
11
    quarter century against one of our deadliest risks."
12
     Would you agree with that statement as it was made in
13
14
             I would agree with that statement as it was
    made in '89 in the context in which it was made.
15
16
     Q Would you agree that the -- throughout the
17
    period of time, that is, since 1964, tremendous changes
    have occurred? Would you agree with that statement made
18
19
    by the Surgeon General in 1989?
         A I would agree with that statement globally, and
20
    I would agree with that statement as the Surgeon General
21
22
    made it, I believe, in the context of what has happened
23
     relative to smoking behavior.
24
         Q Would you also agree that the changes that are
page 361
page 362
    described by the Surgeon General in 1989 as changes that
1
    have taken place from 1965 to 1989 in smoking behavior
 2
    represented nothing less than a revolution in behavior?
 3
 4
         A I think that that is a fair statement. There
    have been substantial changes in smoking behavior over
 5
 6
    that period of time.
 7
            Would you also agree with the statement made by
8
    the Surgeon General in 1989 that the anti-smoking
9
     campaign has been a major public health success?
10
         A I would agree with that.
11
         Q Would you also agree with the achievements that
12
     are cited by Surgeon General in 1989 in the field of
13
     smoking and health had few parallels in the history of
14
    public health?
15
         A I think it is true in multiple context that
     they had a few parallels. They had a few parallels in
16
     terms of the magnitude of the disease created. They had
17
     few parallels in terms of the ability to change and
18
     mobilize society in changing smoking behavior. And they
19
20
    had a few parallels in terms of a focused and organized
     opposition on the part of a specific industry.
21
22
         Q The achievements that are described in the '89
23
    report are achievements that nowhere make reference to
```

```
24
    opposition by the tobacco industry; correct?
page 362
page 363
            I don't believe that that's true. I believe
    that the opposition of the tobacco industry is defined
     in the body of the report.
3
         Q Is there any aspect of tobacco industry conduct
 4
 5
    which is addressed in the '89 report other than
 6
    advertisement?
 7
         A I believe that advertising and lobbying efforts
 8 are addressed in the report.
9
         Q Anything else?
         A I would have to go back to the report to
10
11 examine other issues.
12
         Q Well, certainly one of the things that was done
13 after the '64 report was that there were more Surgeon
14 General reports; correct?
15
         A I don't know what you are saying in relation to
16 a causal inference. Certainly subsequent Surgeon
17 General's reports occurred after 1964.
18
    Q A total of, what is it, 23 reports have now
19
    been issued?
20
    A I don't keep a running number in my head. It's
21 probably somewhere in that number.
22
         Q And the basic goal of those reports was to
23 review all the available scientific evidence on smoking
24 and health; correct?
page 363
page 364
         A That's correct.
1
 2
         Q To make summaries of those, of that data --
   summaries of the data that were accurate and complete
 3
 4 and balanced; correct?
 5
         A That's correct.
         Q And to basically reflect and recite the current
 6
 7
     state of the art in smoking and health science; correct?
 8
         A That's correct.
9
            Is it true that the volume of research that is
10 analyzed and digested in the different Surgeon General's
11 reports is vast?
12
         A I think that's a fair statement.
13
            Literally thousands of different pieces of
14 scientific research are cited, analyzed, summarized and
   encapsulated in recommendations by the Surgeon General
15
16
   since 1964; correct?
17
         A That is correct.
         Q The scientific community looks at the Surgeon
18
19 General reports as being authoritative; correct?
20
         A In general they do, yes.
21
         {\tt Q}\,{\tt } Is there any more reliable authority in the
   field of smoking health since 1964 than the Surgeon
22
23 General reports?
24
         A I think that they are a quite credible, quite
page 364
page 365
    reliable, and are generally regarded as such. I know of
1
    no other set of reviews of smoking and health
 3
    information that is considered more detailed and
 4
    authoritative.
 5
         Q Are you aware of any public health authority
 6 since 1964 who relied upon views stated by the tobacco
 7 industry when they were in conflict with pronouncements
    or statements by the Surgeon General?
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9 Perhaps you could tell me what you mean by 10 "relied on." 11 Q Took action or failed to take action based upon 12 something said by the tobacco industry. 13 A There were multiple examples that I am familiar 14 with, okay, surrounding the issue of regulation with environmental tobacco smoke, where positions were 15 adopted by committees of public health and safety in 16 17 various jurisdictions, where the opposition by the 18 tobacco companies and the statement by the tobacco 19 companies that there was not scientific proof that established that environmental tobacco smoke caused 20 disease was used as a basis for not imposing protective 2.1 22 regulations to prevent exposure to environmental tobacco 23 smoke. That is one example that I am familiar with in 24 some detail where the reliance by individuals who are page 365 page 366 responsible for public health on tobacco industry synthesis of information and expression of that synthesis in terms of whether or not there was a causal 3 4 relationship influenced public policy, influenced the actions on the part of people. 5 6 There are other instances, including testimony 7 in front of Congress for a variety of different pieces 8 of legislation. I cannot cite them from memory with 9 unaided recall, but they certainly exist. There are other instances where choices were made by agencies at 10 the state and local level about allocation of resources 11 12 into various preventive efforts. It is my opinion that 13 those allocations were influenced by both the political 14 power of the tobacco companies and their failure to 15 acknowledge the existing scientific statement that 16 smoking caused disease. Today, isn't it true that the Congressional 17 18 Research Service does not believe that it has been 19 established that environmental tobacco smoke causes 20 disease? 21 A I don't believe that that's a fair reading of 22 those reports. 23 Q Well, what do you think the view of the 24 Congressional Research Service is? page 366 page 367 1 I think that the review of the Congressional 2 Research Service in its reports was that they don't 3 believe epidemiologic data in one report. And in another report they established that various studies had 4 5 various limitations and they did not draw a conclusion. 6 I'm not aware that they drew a conclusion that 7 there was evidence after a review of all the evidence to 8 conclude that there was not a scientific relationship 9 established between smoking and -- environmental tobacco 10 smoke and disease. 11 Well, let me put my question, then, in the 12 following way: Congressional Research Services specifically looked at the issue of whether 13 14 environmental tobacco smoke causes disease, does it not? 15 A I'm not sure that I would accept that 16 characterization. They accepted a charge from Congress 17 to examine certain specific aspects of the data that 18 exists. And they produced two reports on that specific 19 charge.

20 Q Are you aware of any public health authority 21 since 1964 who has taken as true any statement made by any tobacco company on smoking and health issues where 22 23 it is -- where the statement by the tobacco companies is 24 in conflict with Surgeon General reports? page 367 page 368 I mean, that's a very strange statement for me 1 2 to respond to. I think that it is true, during the 3 period of time that I've been involved in public health, 4 that very few public health authorities have been willing to accept any statement by a tobacco industry 5 representative that was in conflict with the Surgeon 6 7 General's report as something other than an attempt to 8 misrepresent the scientific data. 9 That is not the same thing as saying that those 10 individuals were not constrained in terms of their 11 actions by the political position adopted by the tobacco companies that the science had not proven causality. 12 13 But I don't think that in their heart of hearts as a scientist they believed that the tobacco industry 14 15 was even under the remotest of circumstances telling the truth when it said that the scientific case had not been 16 17 established. 18 I think it is, perhaps, one of the great 19 corporate tragedies that for an industry as large as the 20 tobacco industry, that the representatives of the public health community nearly universally expected to be lied 21 to when they were spoken to by the public -- by the 22 23 tobacco industry. 24 MR. SCHROEDER: Would you mark that one for me, page 368 page 369 1 please? BY MR. BERNICK: Q Do you know of any medical association or 3 public health authority since 1964 who has regarded the 4 tobacco industry as a reliable source of information on 5 the question of whether cigarettes cause disease? 6 7 A I'm not sure what your question is intended to 8 reflect. There are certainly a number of individuals 9 who have relied on the tobacco industry scientists for certain components of the information. 10 11 Q Dr. Burns, I'm sorry. I listened now to two 12 different answers that were long and nonresponsive. And 13 you've now told me again that you're not sure what it is that I'm asking. I'll withdraw the question. 14 15 Α Okay. 16 Q And I'll put it to you again very, very simply. 17 Because I'd just like an answer to it. 18 Are you aware of any medical association or 19 public health authority which since 1964 has regarded 20 the tobacco industry as a credible source of information 21 on the question of whether cigarettes cause disease? 22 A I am uncertain about the period immediately 23 following 1964. But certainly for most of the period that I have been involved in this issue, from 1975 24 page 369 page 370 1 onward, my experience with individuals in public health 2 is that they universally expect that the tobacco company 3 will lie to them about the relationship, scientific relationship and scientific evidence establishing that

cigarette smoking causes disease. 5 Q Are you aware of any medical association or 6 7 public health authority since 1964 who has looked to the 8 tobacco industry as a credible source of information on the question of whether cigarettes cause disease? 9 MR. GRUENLOH: Objection; asked and answered. 10 THE WITNESS: Could you define for me what you 11 mean by "information"? When I've tried to answer that 12 13 question in terms of content information, you've told me 14 that that's not what you want. What is it that you're 15 asking me to respond to? 16 BY MR. BERNICK: 17 Information supplied by the tobacco industry, views expressed by the tobacco industry on the question 18 19 of whether cigarettes cause disease. 20 Okay. Are you restricting that to the 21 statement, "cigarette smoking does not cause disease"? Or are you including within that the body of information 22 23 on the component parts of the science used to establish 24 that? Those are two -- many people, the Surgeon page 370 page 371 General's report included, have relied on published data 1 from the tobacco companies about the composition of 2. 3 cigarettes, about smoke chemistry, about a variety of 4 other factors, that are important pieces of the 5 information that establishes that smoking caused disease. That is, in general, relied on and felt to be 6 7 within certain bounds credible. That's not the same 8 thing as relying on the tobacco industry's statement 9 that the science has not established that smoking causes 10 disease. 11 Okay, that's fair enough. Now, I'll rephrase the question. Are you aware of any doctor, medical 12 association or public health authority who since 1964 13 has regarded the tobacco industry as a credible source 14 15 of statements regarding whether causation of disease has 16 been established? 17 Okay. I am aware that when these issues come 18 up before public health authorities for purposes of 19 altering any form of public policy or developing any 20 major tobacco intervention, that it is common for 21 tobacco industry representatives to testify in front of those hearings. They are, in general, treated 22 23 respectfully in that setting. And it is my opinion that 24 their testimony forms the basis for actions, or more page 371 page 372 1 appropriately inactions, on the part of many of those bodies. 2 3 I am not aware of a voluntary health agency, 4 with the exception of the AMA, who from 1964 on has said 5 that, "We believe that the tobacco industry statement 6 that smoking does not cause disease is a credible 7 statement." 8 If I'm not answering your question, tell me 9 where I'm missing the point, and I'll do my best to 10 answer it. But that's as complete as I can be. MR. SCHROEDER: Mark that. 11 12 BY MR. BERNICK: 13 Q Are you aware of any doctor, medical 14 association, or public health authority since 1964 who 15 has stated publicly that causation of disease from

smoking has not been established? 16

> A My understanding is that that statement was made by the American Medical Association in conjunction with a gift by the tobacco industry for its research and education fund; that they were maintaining the position that the causation remained to be established.

Do you have any documentation of the American Medical Association since 1964 taking the position that causation has not been established?

page 372 page 373

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- I don't have a specific document from recall or sitting here in front of me that I can cite.
- Are you aware of any situation where any doctor, medical association, or public health authority since 1964 has recited the views of the tobacco industry on causation as being true?
- A It is my understanding that a variety of health 8 committees for unions, a variety of Congressional committees, a variety of other organizational structures, have produced descriptions of the relationships of smoking and health, in particular environmental tobacco smoke and health, an area that I'm more conversant with specifically, that were close to 14 identical to those of the tobacco industry. And that 15 therefore, they were either parroting those or accepting 16 them and using them as a basis for their opinion. I am unaware of a specific voluntary health organization which has done that.
- Q Are you aware of -- setting aside environmental tobacco smoke, just talking about mainstream smoke, that is, actually smoking, are you aware of any doctor or medical association or public health authority that has taken the statements made by the tobacco industry about the health effects of smoking as being true since 1964? page 373 page 374
 - I mean, I'm having some difficulty figuring out where I haven't answered your question. Help me.
 - Q You asked me before -- it's a very broad question, is what you're saying. I'm now just breaking out very specific things to ask you so that we don't get into dialog about what it is I'm asking you and the scope of it. I'm just asking you very, very simple pieces.

This piece, and I'll say it again, are you aware of any doctor, medical association, or public health authority that has taken statements made by the tobacco industry on the question of causation since 1964, has taken those statements as being true? And I want to set aside for purposes of this question environmental tobacco smoke.

A It is my understanding that those authorities 17 responsible for regulating advertising, for increasing 18 taxation, for a variety of other public policy interventions which are felt to be effective in altering smoking behavior, have accepted as valid arguments by the tobacco companies that advertising does not influence adolescent behavior --

23 Q Dr. Burns, I didn't ask you about advertising and adolescent behavior. I'm asking you about causation 24 page 374

page 375

of disease. 1 A Okay. 2 MR. BERNICK: Let's just mark the record. I'm 3 4 not even going to pursue this line. 5 THE WITNESS: That's fine. 6 MR. BERNICK: We'll just take it up with the 7 judge. I'm just tired of going through this. THE WITNESS: I had thought I answered your 8 9 question completely on causation of disease. 10 MR. BERNICK: No. I asked you about causation of disease, and now you're talking about advertising. 11 They have absolutely nothing to do with one other. I 12 can't continue on this basis. I'll just asking you 13 something else and we'll take it up with judge. 14 THE WITNESS: Well, if you had allowed me to 15 16 complete my answer, I might have been able to show you how they had something to --17 18 MR. GRUENLOH: You know, Dr. Burns, we've got 19 it on the record. Let's go ahead. 20 THE WITNESS: Okay. 21 BY MR. BERNICK: Q Are you aware of any doctor, medical 22 association, or public health authority that has recited 23 24 the industry statements regarding addiction as being page 375 page 376 true since 1964? 1 A I don't understand your question. There are 2. 3 several organizations that have not said that smoking 4 was addictive during that period of time. That was the 5 position of the tobacco industry at that period of time. I don't believe that those organizations relied 6 7 exclusively on the tobacco industry's analysis of that 8 body of information to form that opinion. 9 I didn't ask you whether they relied Q 10 exclusively. 11 A Look, I'm trying to figure out what it is 12 you're asking. 13 Q You're a very smart man; you know exactly what 14 I'm asking. 15 A I don't. The tobacco industry makes a statement about 16 17 addiction. They've done so since 1964. True? 18 A That's correct. 19 Q All I'm asking you is, are you aware of any 20 doctor, any medical association, or any public health 21 authority that have recited those positions, those 22 tobacco industry positions as being true on that 23 subject? 24 A I don't understand your question. Can I page 376 page 377 1 clarify where I don't understand it? 2 3 MR. GRUENLOH: Would you like help on this? 4 THE WITNESS: Okay. I don't understand what you're asking me. There are organizations which have 5 6 clearly expressed the same position as the tobacco 7 industry. Okay? That is true. Therefore, in that 8 answer there are many organizations who have said that. 9 Okay? If you're asking me whether they took the 10 statement by the tobacco company and said, "We believe 11 the statement by the tobacco company as a tobacco

company statement is true," I don't think any 12 13 organization would ever do that with any statement by 14 any external group. They would examine the data 15 internally. 16 And so certainly organizations have made 17 statements on addiction that are -- "we do not believe that cigarette smoke -- that nicotine is -- we do not 18 19 know whether the addictive agent in cigarette smoke is nicotine," or that "we don't know whether cigarettes are 20 addictive." That is the same position maintained by the 21 22 tobacco companies. But I don't believe that they took that position from the tobacco company statement. 2.3 BY MR. BERNICK: 2.4 page 377 page 378 1 Are you aware of any doctor, medical association, or public health authority who formulated 2 3 their position on addiction since 1964 on the basis of statements made by the tobacco industry? 5 A I am unaware of any physician or organization that would formulate their opinion in that way, and 6 7 therefore, I am not aware of any organization that has 8 done that. 9 Are you aware of any doctor, medical 10 association or public health authority that has 11 formulated its position on whether cigarettes cause 12 disease since 1964 on the basis of any statement made by the tobacco industry on that question? 13 A "Any statement" is restricted to causation? 14 Q Causation of disease. 15 Okay. Agencies and groups of professionals who 16 Α 17 examine this issue for purposes of reaching a judgment, 18 examine the data upon which that judgment is reached. 19 They do not rely on external statements by, particularly, an industry group as the basis for drawing 20 21 their conclusion. 22 So since no organizations form opinions in that 23 way, I know of no organization that did form its opinion in response to the tobacco industry statement. Or used 2.4 page 378 page 379 or relied on the tobacco industry's statement in 1 synthesis of the data on causality as a principal piece 2 3 of the information that they used to formulate their 4 opinion. 5 Q It's been in the Surgeon General reports in 1960 -- since 1964 that tobacco smoke contains various 6 7 carcinogens; correct? 8 That's correct. 9 The fact that tobacco smoke contains 10 carcinogens has been no secret in the scientific 11 community since the very early 1950s; correct? 12 That is correct -- well, mid 1950s, that's Α 13 correct. 14 Well, in fact, even before the mid 1950s, the 15 fact that tobacco smoke, for example, contained benzpyrene was published in Reader's Digest in 1950; 16 17 correct? 18 It is correct there was an ongoing scientific 19 discussion at that time as to whether or not it came 20 from the tobacco or from the paper and its exact 21 derivation. But certainly -- I mean, there's no 22 substantive reason to quibble about this. By the mid

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1950s it was clear that it came from the tobacco.
2.3
24
    was evident in tobacco smoke from cigarettes that -- as
page 379
page 380
    they were conventionally manufactured much earlier than
1
            It's been no secret from the scientific
 3
 4
     community that cigarettes contain additives since the
     same period of time, long before 1964; correct?
 5
 6
         A I think that that's an overly broad statement.
 7
    It was generally understood by people who were
    interested that things were added to tobacco. Up until
 8
    fairly recently what was added to tobacco, and
 9
     specifically what was added to tobacco for individual
10
11
    cigarettes, was considered a trade secret and not
12
    available to the general scientific community.
13
         Q Well, a whole series of additives are described
14
    in the 1964 report; correct?
15
         A That's correct.
16
            So the -- while the full list of additives may
    not have been set forth in the '64 report, the 1964
17
18
    report does disclose the fact that a variety of
    additives are used in the manufacture of cigarettes;
19
20
    correct?
21
         A It does describe that some additives are used.
22 It also does not make any attempt to portray its
    description of additives as either comprehensive,
23
     complete or fully discussed in terms of its
24
page 380
page 381
    implications.
1
      Q Is it true that Reynolds published a long list
 2
 3
    of additives used in the manufacture of cigarettes in
    the early 1970s? Have you looked at that?
 4
         A I have looked at a list. There is a very long
 5
    list of things that might be used. As I said, it is my
 6
 7
    understanding from fairly detailed knowledge that the
    tobacco companies did not disclose what constituents,
8
9
    what additives were actually used, the amount that were
10
    actually used, and particularly the amounts that were
11
    actually used for individual brands of cigarettes until
12
    quite recently that. That those issues were defined by
    the tobacco companies as trade secrets and not to be
13
14
    made publicly available to the general scientific
15
    industry.
16
            Are you a familiar with the fact that in 1984
17 the tobacco industry submitted to the Department of
18 Health, Education and Welfare a list of additives used
19
    in the manufacture of cigarettes?
20
         A I'm quite familiar with the fact that they
    submitted that list. And that requirements for
21
    submission was that the list be kept in a safe, not
22
    disclosed, and that no more than five individuals total
23
     could ever see the list.
24
page 381
page 382
            I didn't ask you that. Did they submit a
1
         Q
 2
     list --
             You asked me whether I was familiar with it.
 3
 4
            Do you want to have the question -- let's have
         0
 5
   the question reread.
 6
         A Okay.
 7
             (Record read.)
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MR. SCHROEDER: Would you mark that, too?
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9
   BY MR. BERNICK:
10
       Q It's a yes or no question, Dr. Burns.
11
         A I don't believe that's a yes or no question.
12
         Q "Are you or are you not familiar" is a yes or
13
    no question.
    A I think that you believe it is. I believe --
14
15
    when you ask questions in a context, they occasionally
16
    need an explanation.
17
            Are you aware of any additives actually used in
18 the manufacture of cigarettes that were not included in
19 the list that was provided to HEW in 1984?
20
        A I have never seen the list provided to HEW in
21 1964 and was not --
22
        Q
            1984?
         A 1984. And therefore, am not in a position to
23
24
    answer your question. That list, as I said, was
page 382
page 383
1
    restricted to five individuals. I was not one of those
    individuals.
         Q Dr. Burns, let's talk a little bit about the
 3
    formation of the TIRC. You're familiar that that
 4
 5
    ultimately became known as the CTR; correct?
 6
         A That is my understanding.
7
         Q And CTR was an organization that in part
8
    provided grant funding for people to do scientific
9
    research; correct?
         A In part, that's my understanding.
10
11
         Q And the formation of the CTR or TIRC grant
12 program was announced through what's known as the Frank
13 statement that was published in early 1954; true?
14
        A Well, as I understand it, technically they
15 announced the intent to form it, but yes.
        Q Are you familiar with the fact that Hill and
16
17 Knowlton was consulted in connection with the formation
18
   of the TIRC or CTR?
            I am.
19
         Α
         Q Have you looked at the documentation that was
20
21 associated with the formation of the TIRC and the
22 issuance of the Frank statement?
        A I have seen some documents that relate to that.
2.3
24
    I'm not specifically certain what documents you're
page 383
page 384
1 referring to.
2
        Q Have you made an effort to gather all the
 3
    documentation that's available in the litigation
    pertaining to the formation of TIRC and the issuance of
 4
 5
    the Frank statement?
 6
         A I made an effort to collect as much of that
    information as I could find. It is my understanding
 7
 8
    from review of that that it is an incomplete description
    of all of the documents that are likely to be available.
9
10
    Or likely to have been available at one point in time.
         Q Have you heard the claim that the formation of
11
12
    the TIRC/CTR was a public relations effort?
13
         A Yes. And since Hill and Knowlton was a public
14
    relations company, that is consistent with contracting
15
    with them to help form it.
        Q Do you know whether the formation of the TIRC
16
17
    was something that was Hill and Knowlton's idea?
18
        A I'm not sure what you're -- what you're saying.
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Hill and Knowlton was contacted by, as I understand it, 19 20 the tobacco companies to help them deal with this issue. I don't know specifically whether an individual at Hill 21 22 and Knowlton recommended the formation of this scientific group, whether that came from individuals 23 24 within the tobacco companies, or whether that was part page 384 page 385 1 of a joint discussion that identified that as a 2 reasonable course of action following their meeting. Q Okay. I guess what I'm asking is, do you have 3 any opinion or will you be offering any opinion that the 4 formation of the TIRC was Hill and Knowlton's idea? 5 A If asked, I would give the same answer that I 6 7 just gave you. I don't expect to be asked that 8 question. 9 Q But if asked, would you say that it was, or 10 would you say that you just don't know? A I have answered the question for you. Okay? I 11 12 would give you the same answer to the same question --Q Well, I'm just not sure. I don't understand --13 I guess I'm not clear on what your answer really is. 14 15 A My answer was that I don't know whether or not 16 the formation of the TIRC, okay, was generated by 17 someone from Hill and Knowlton as a recommendation, 18 whether it was generated as a recommendation by one of 19 the individuals from one of the tobacco companies, or 20 whether it was a product of the joint discussion that 21 occurred at the meeting. 22 Q One of the purposes that is stated in the Frank 23 statement for the TIRC -- the purpose that is stated in the Frank statement for the TIRC is to sponsor the 24 page 385 page 386 conduct of scientific research; correct? I believe that's correct. 3 Do you have any evidence, Dr. Burns, that when the TIRC was formed and the Frank statement was issued, 4 that the intent of the tobacco industry was only to 5 6 achieve public relations purposes and not to conduct 7 scientific research that was bona fide and relevant to the issue of smoking and health? 8 9 A That is a complex and multiple-part question 10 that I'll be happy to address. The -- it is my 11 understanding that a principal reason for the TIRC being 12 created was a public relations reason. And that the 13 potential conflict between its public relations activity 14 and the efforts to present it as an objective scientific 15 resource were what led to the creation of the lobbying 16 group, the Tobacco -- I'm blocking on it now. That's 17 awful. They were around so long. Tobacco Institute, to 18 separate those two activities. 19 It is my understanding that they attempted to 20 fund credible research, that I don't know the specifics 21 of the intent of the initial funding as to whether that 22 initial funding was specifically directed at answering 23 the questions about smoking and disease. 24 The grants that were funded and the research page 386 page 387 1 produced from those very initial studies would suggest 2 that there was an effort in that direction. Subsequent 3 research funding would lead to a different conclusion.

But your question related to the initial organization of 4 5 it, and that's what I'm trying to respond to it. Q Let's break this down, because maybe I didn't 6 7 put the question as accurately as I should have. I'm talking about the purpose that the tobacco industry had 8 9 in forming the TIRC. That's what my focus is. What was intended at the time TIRC was formed. We'll just work 10 11 with that to begin with. 12 A My understanding --13 Q I haven't put a question. 14 A I'm sorry. 15 Q That's just my focus. A Okay. 16 17 At the time that the TIRC was formed, do you 18 have any evidence that the tobacco industry did not 19 intend to conduct bona fide scientific research through 20 the TIRC? 2.1 It is my understanding that there was an intent 22 to conduct legitimate scientific investigation through 23 the TIRC in the grants funding program. There was also an intent to use the TIRC as a public relations activity 24 page 387 page 388 to support the tobacco industry's position on the 1 2 causation of disease. That both of those were part of 3 the reasons for forming the TIRC. But certainly, I 4 believe that there was an effort made to fund scientific 5 research that was credible, and in the early stages was related to tobacco. 6 7 Q The TIRC was set up to have a Scientific 8 Advisory Board; right? 9 A That's my understanding, yes. 10 The basic organizational structure was then that the tobacco industry would provide money to the 11 TIRC, that the TIRC would receive grant proposals from 12 outside scientists, that the SAB would review and 13 14 approve them, and then funding would be provided to the approved grant recipients. Did I get that right, as you 15 16 understand it? 17 A That is not my understanding of how the process 18 worked. That is my understanding of what was presented to the public as to how the process worked. My 19 understanding of how the actual process worked is that 20 21 there was considerable oversight by the tobacco companies, and particularly the tobacco company lawyers, 22 23 as to what activities the TIRC funded. 24 Q Let's break that one down again too. page 388 page 389 At the time the TIRC was created and throughout 1 2 the existence of the TIRC and the CTR, there has been a 3 Scientific Advisory Board; correct? 4 That's my understanding. 5 And the function that was to be served by the 6 Scientific Advisory Board was to approve grant 7 applications, correct? 8 That was the purported function, that's Α 9 correct. And isn't it true that the idea of having a 10 11 grant program, with grants approved by the scientific --12 by a group of outside experts, that that was something 13 that was actually recommended to the tobacco companies 14 by outside scientists in the early 1950s?

```
It would not surprise me that was true.
15
    don't have a specific document that establishes that.
16
    But it would certainly be the kind of advice that
17
18
     outside scientists would give to the industry.
19
          Q What the tobacco industry committed to in the
20
    Frank statement was that the Scientific Advisory Board
     would be comprised of distinguished men from medicine,
21
22
     science and education who would be invited to serve on
23
     the board; correct?
24
          A I believe that is what they committed to. I
page 389
page 390
    don't believe that they meant to restrict it to men.
1
         Q Okay. Now, in fact, if we take a look at the
 2
 3
    people who have served on the Scientific Advisory Board
 4
    over time -- have you examined the people who served on
    the Scientific Advisory Board over time?
 5
 6
         A I've not done a comprehensive evaluation of
 7
     each of the boards during each of the years. I'm
8
     generally familiar with the individuals on those boards,
9
    and many of them have distinguished scientific
10
    reputations.
          Q Are you aware of any member of SAB, that is,
11
12
    anybody who served on the SAB, who wasn't qualified to
13
    make grant funding decisions in the field of smoking and
14
    health?
15
          A I guess that depends on what you mean by the
    "field of smoking and health." There certainly were
16
    scientists who were on that board who were well
17
18
    qualified to make funding decisions on basic science
19
    that could ultimately have some relationship to tobacco.
    As to whether or not they were qualified to specifically
20
21
    target research to answering the question of whether
     smoking caused disease, I think that the boards, as
22
     selected, were not selected to contain a body of
23
     individuals who would be focused on answering that
24
page 390
page 391
1
    question. They were largely selected from individuals
 2
    who were principally focused on the basic mechanisms of
    disease occurrence, and therefore, were interested in
 3
    basic science rather than answering the applied question
 4
    of whether tobacco caused disease.
 5
 6
            Well, regardless of what the direction of the
 7
    research was, were there any members of the SAB, that
 8
    is, people who actually served on the board, who are not
9
    distinguished men from medicine and science and
10
     education?
11
         A I've not conducted a detailed review of every
12
     individual who is on the board. It is not my
13
    understanding that the board was composed of individuals
14
    who do not -- who did not meet that criteria. I have no
15
     individual in mind who did not meet that criteria.
16
            Are you aware of any evidence that any member
17
     of the SAB felt that they were part of a scientific
     process that was not really a bona fide scientific
18
19
     process, but was being pursued in bad faith?
20
          A I have not seen documents from or
21
    correspondence from the SAB expressing their individual
22
     opinions on that issue, either pro or con.
23
        Q Are you aware of anybody from the SAB who has
     ever spoken out and said that they understood their job
page 391
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page 392 1 on the SAB was to support an effort to deceive the public? A I have never heard such a statement, and it would be very surprising for an individual to -- who is 5 sitting on a board to make that kind of statement. MR. SCHROEDER: Would you mark that? 6 7 BY MR. BERNICK: 8 Q Are you aware of who the scientific directors 9 of the CTR have been? 10 A I can't from memory give you a complete list. 11 I know that there are -- have been several. Q Do you recall that the first scientific 12 13 director of the CTR was Dr. Clarence Cook-Little? 14 A I recall that. 15 Do you recall that he was on the -- he was the 16 director from 1954 to 1971? A I don't have those specific dates in memory. 17 18 I'm perfectly willing to accept that those are true. 19 Q Is it true that Dr. Little was former president 20 of the University of Michigan, former president of the University of Maine, founder of the Jackson Memorial 21 Laboratory, managing director of the American Cancer --22 23 The American Society for the Control of Cancer, which 24 became the American Cancer Society, and president of the page 392 page 393 American Association for Cancer Research? 1 2 A I've not conducted a detailed review of 3 Dr. Little's background. The description you have given me is, indeed, consistent with my understanding of his 4 5 background. 6 Would it be fair to say that Dr. Little, the 7 first scientific director, was a man of unimpeachable 8 integrity and national repute? A I think that in the light of events that have 9 10 occurred over time, there has been some question about 11 whether that would be a fair characterization of 12 Dr. Little. I think at the point of time at which he 13 was appointed there would not have been a substantive 14 criticism on that basis. Q I see. You don't believe that Dr. Little acted 15 16 with integrity? 17 A I think that it is difficult for me to believe 18 that an objective scientist of -- acting with integrity 19 would have continued to adopt the positions that Dr. Little was adopting. And it is my belief, okay, 20 21 without a document to substantiate it, that his 22 responsibilities and interactions with the tobacco 23 industry colored his objectivity in terms of deciding 24 what the science had concluded. page 393 page 394 1 I want to ask you very specifically. Integrity pertains to somebody's personal ethics; correct? A I'm referring to scientific integrity, which is 3 4 whether or not the conclusions that you are expressing 5 are based upon the data that you have reviewed, or upon your personal perspectives and biases about what those 6 7 conclusions might be interpreted to mean. I'm not 8 suggesting that Dr. Little was guilty of any kind of 9 financial irregularity or that he was accepting payments 10 in order to alter his positions.

```
Do you believe that Dr. Little was acting in
11
12
    bad faith in the activities that he pursued as the first
13
     scientific director of CTR?
14
         A I think Dr. Little was acting in very good
     faith relative to the expectations of the people who had
15
16
    hired him. I think that he was not acting in good faith
     as a scientist, interpreting data for the public about
17
18
    whether cigarette smoking caused disease.
19
         Q Do you believe that Dr. Little knew that he was
20
    part of some campaign to deceive the American public?
21
         A I think that what Dr. Little knew or didn't
22 know is beyond my ability to define with any degree of
    precision. I think that having looked at the evidence
23
    myself, and having reviewed some of Dr. Little's
24
page 394
page 395
     statements, it is very difficult for me to believe that
1
 2.
    his objectivity in reviewing that data was maintained
     and that his review of that information was not
 4
     influenced by his association with the tobacco industry,
     and that, therefore, he was not fulfilling his
 5
 6
     obligation as a scientist to examine the data
     objectively, and he was not fulfilling his
 7
 8
    responsibility to the public to communicate what the
9
    scientific community believed to be true on the issue of
10
    smoking causing disease.
            Do you believe that Dr. Little intentionally
11
12
    deceived the American public on any issue?
         A I don't have a specific knowledge of
13
14
    Dr. Little's state of mind at the time he made those
15
    statements. What I've said is that the statements are
    not consistent with what I believe to be an objective
16
17
    review of the scientific data available.
18
         Q I'm just asking, as an expert, are you prepared
19 to say that Dr. Little attempted to deceive the American
20
    public?
             MR. GRUENLOH: I think Dr. Burns has said that
21
22
    he has no idea what his state of mind --
             MR. BERNICK: This is another speaking
23
24 objection, Counsel.
page 395
page 396
             MR. GRUENLOH: Object to form.
1
 2
    BY MR. BERNICK:
 3
     Q Do you want me to put the question to you
 4
    again?
 5
        A Certainly.
 6
         Q Do you believe that Dr. Little was acting to
7
    deceive the American public?
8
             MR. GRUENLOH: Object to form.
             THE WITNESS: I believe that Dr. Little's
9
10
    actions deceived the American public as to the state of
11
    the scientific knowledge on whether smoking caused
12
    disease. I am not in a position to define Dr. Little's
13
     state of mind in order to characterize whether that was
14
     something that he had convinced himself to be true, or
15
     whether he was saying that, having known that it was not
16
    true. So I cannot tell you what his intent was.
17
             I can tell you that those actions did not
18
    reflect the scientific consensus at that time, and that
    my view of that scientific information would lead me to
19
20
    believe that it is very difficult that an objective
21
     scientist with the responsibility of reaching that
```

judgment would have reached the conclusions Dr. Little 22 did and express them. And therefore, I raised the 2.3 24 question as to whether he was acting in a way that was page 396 page 397 objective and independent of his association with the 1 tobacco industry. BY MR. BERNICK: 4 Q Are you familiar with any of the other 5 scientific directors, Dr. Gardner, Dr. Summers, or 6 Dr. Glenn? 7 A I have never met them personally. I am generally familiar with them. 8 9 Q Did any of them lack the qualifications to act 10 as scientific director for CTR? 11 A I am assuming that since the -- since CTR hired 12 them based on a set of criteria, that they fulfilled 13 those criteria. I believe that each of them had a 14 credible scientific background and were credible in the 15 position to administer a grant program. 16 Q Are you aware of any deceptive statements that 17 were made by Dr. Gardner, Dr. Summers, or Dr. Glenn? A I don't have a specific knowledge as I sit here 18 19 of a specific statement at a specific point in time. It 20 is my understanding that they persisted in the statement 21 that the science had not established that smoking caused 22 disease. But I don't have a specific instance in mind. Q It's true, is it not, that the grant program 23 ultimately executed by -- or I should say funded by CTR 24 page 397 page 398 1 was an extensive one? A It certainly funded a substantial body of research and provided a substantial level of funding. 3 Q I want to set aside the question of research 4 conducted into the central nervous effects of smoking. 5 I want to set that to one side. 6 7 A Okay. 8 Q Are you aware of any evidence that the SAB at 9 any point in time was told what they could or could not approve by way of grant proposals or contract proposals? 10 A My understanding was that the SAB did not 11 approve all of the aspects of the funding of monies that 12 13 came through TIRC. Of those that came through the SAB 14 for approval, they voted on those, and then there were 15 administrative decisions about what got funded. There was also some selection as to what grants 16 17 were consistent with the mission, and therefore, what 18 grants would be submitted to the SAB. I'm not aware of an instance where the SAB was told that they could not 19 20 fund studies in certain areas; that that was done 21 through other mechanisms besides telling a group of 22 scientists that they cannot do something. And that my 23 review of the documents on that issue leads me to 24 believe that the people running the TIRC recognized that page 398 page 399 they could not tell a distinguished group of scientists 1 what they could not fund. And that there were other 2 3 mechanisms that could be used to change the nature of 4 the work that was funded. Q Setting aside research regarding the central 6 nervous system effects of smoking, are you aware of any

```
grants that were approved or contracts that were
 8 approved for funding by the SAB, but they ultimately
9 were not funded by the CTR?
10
        A It is my understanding that there were grants
11 routinely approved for funding that were not funded.
12
    That is standard with most grant processes.
13
         Q Name one. You say that that's standard. I'm
14
    not asking you about what is standard. I'm asking you
15
    about CTR.
16
         A I don't have a specific grant in mind on a
17 specific SAB. But many grants are approved for funding
18 and not funded. That's true of all funding agencies.
             MR. SCHROEDER: Mark that.
19
20 BY MR. BERNICK:
21
     Q Dr. Burns, I'm not asking you about all funding
22
    agencies.
23
     A I don't have a specific instance of mind of a
    specific grant.
24
page 399
page 400
            Are you aware of any group of grants or any
1
     category of grants that the SAB approved for funding but
    that were not ultimately funded by the CTR?
 3
 4
         A Independent of the grants on central nervous
 5
     system?
 6
         Q Yes, separate -- setting aside central nervous
 7
    system.
8
            Okay. That is the principal area where I have
    seen documents that the funding authority of the SAB was
9
10
    subverted. I don't -- or funding approval of SAB was
11
    subverted. I don't have a specific instance other than
12 that of the -- of documents that describe a subversion
13 of the SAB's funding priorities.
             MR. SCHROEDER: Mark that.
14
15 BY MR. BERNICK:
         Q I'll try one more time.
16
         A I told you that I don't have a specific
17
    instance in mind. What more do you want?
18
19
         Q Because I asked you -- you told me specific
20 instance. You told me that twice. I asked you for a
21 group or category or collection of some kind, so that
    we're not just talking about there's one, or there's
2.2
    another. I'm asking, are you aware of any group or any
23
24
     category, any kind of characterization of grant
page 400
page 401
    proposals or contract proposals that were approved for
1
    funding by the SAB but that ultimately were not funded
 3
    by the CTR? Setting aside again the research in the
 4
    late 1970s into central nervous system effects of
 5
    smoking.
 6
            It is my understanding that the process of the
 7
    research funding was such that grants were not presented
 8
    to the -- please let me finish. Were not presented to
 9
    the CTR board and then not available for funding. And
    therefore, I'm not aware of a body of grants that had
10
    been presented to the CTR board and not funded.
11
12
         O I --
13
             MR. GRUENLOH: Hold on a second.
14
             MR. BERNICK: At this point --
15
             MR. GRUENLOH: Mr. Bernick, hold on a second.
16
             MR. BERNICK: I'm not going to ask him a
17
    question.
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MR. GRUENLOH: No, hold on one second. 18 MR. BERNICK: I'm not going to hold on. If you 19 20 are going to interrupt the deposition, we will end the 21 deposition right now. MR. GRUENLOH: Then let's go off the record. 22 23 MR. BERNICK: No, we're not going to go off the 24 record. page 401 page 402 1 MR. GRUENLOH: The faces that you're making, 2 the little sighs, the laughs, this is disrespectful. 3 And we will discontinue this deposition at this point if 4 it continues. MR. BERNICK: I'm expressing at this point 5 6 frustration of the witness' refusal to answer the 7 question. I'm going to discontinue this line of examination. This will be the second line of 8 9 examination at the very least that we're going to raise 10 with the judge. 11 MR. GRUENLOH: It's the same line of 12 examination that you said you were going to discontinue 13 before. MR. BERNICK: No. 14 15 MR. GRUENLOH: You never left it. 16 MR. BERNICK: It's a completely different one. 17 Q Are you aware of any evidence that any member 18 of the SAB ever acted in bad faith? A Could you define for me what you mean by bad 19 faith in relation to membership in the SAB? 20 21 Q That they knowingly failed to do their job, 22 that they knowingly falsified recommendations or approvals, anything that would mean that they are 23 24 knowingly failing to do their job as scientists and as page 402 page 403 members of the SAB. 1 2 A It is my understanding that the scientists on the SAB fulfilled the responsibilities they were asked 3 to fulfill by the TIRC in terms of reviewing and 4 5 approving grants. It is my understanding that they tended to be somewhat biased to their own research and 6 7 their own institutions in terms of those grant approvals, but that that was not something that was of 8 9 substantive concern to the CTR and was not considered to 10 be an inappropriate or irresponsible action on the part 11 of those members. 12 Q Are you aware of any research sponsored by CTR 13 that was falsified? 14 I don't have a specific recall of all of the 15 research funded by CTR. I am not aware of research that 16 was published where the data was deliberately altered in 17 publication. 18 MR. SCHROEDER: Would you mark that one for me, 19 please? 20 BY MR. BERNICK: 21 Q Are you aware of any research that was 22 sponsored by CTR where the publication of the research 23 was knowingly altered or changed in any way so as not to accurately reflect the results of the research? 24 page 403 page 404 A It is my understanding that there are at least 2 two instances where that has come into question. One

was the work by Dr. Humberger (phonetic), Freddie 3 4 Humberger, where he was asked to change the description 5 of his work as it appeared in publication. 6 Did he? 7 My understanding is that he modified it 8 somewhat, but that ultimately he did not agree to do 9 10 The second example was in work that has been 11 funded, I believe, on a contract where the examination 12 of animals over a long period of time was terminated, and a very long, detailed report of that was written 13 14 that one of the principal investigators of that effort feels did not reflect the body of information that that 15 research had demonstrated. 16 17 Q That's the MAI contract? 18 A It's Dr. Henry, I believe. Q She worked on the MAI contract? 19 20 A I'm simply giving you the information I have, 21 and not trying to contradict you. 22 Q Isn't it true that Dr. Henry wrote the article that came out in the Journal of National Cancer 23 24 Institute reflecting the results of that work? page 404 page 405 1 I am not specifically conversant with that article. I'm referring to a larger report on that body 3 of work. The larger report is called the Blue Book? 4 Q That's correct. 5 6 Q Isn't it true that the Blue book was written by 7 Dr. Henry and Dr. Curry? A I don't believe that they felt that the final 8 9 draft of that version reflected their initial input. At 10 least as I recall from having read Dr. Henry's 11 deposition. 12 Are you really familiar enough with that 13 contract to express expert opinions regarding 14 falsification of research or improper statements of 15 research, Dr. Burns? 16 MR. GRUENLOH: Object to form. 17 BY MR. BERNICK: 18 Q I'm just asking you. A You had asked me for examples. I tried to give 19 you an example. I'm certainly expert enough in the 20 21 conduct of research and those areas of research to 22 review that in more detail and offer more detailed 23 comments on it. Q At this point in time have you done work page 405 page 406 sufficient to offer expert opinions regarding the 1 2 conduct of research by MAI? 3 MR. GRUENLOH: Same objection. 4 THE WITNESS: I have done sufficient work to 5 believe that the conduct of that research, okay, resulted in a document being produced that I believe is 6 7 not consistent with the internal data contained, and 8 that I believe the -- one of the principal investigators 9 has characterized as not being a scientifically valid 10 expression of that work. I would be in a position to 11 offer that opinion. If it is an issue that requires 12 more detailed discussion, then I would obviously need a 13 more detailed review to provide that detailed

```
discussion.
14
15
   BY MR. BERNICK:
         Q Dr. Burns, are you aware of any medical
16
17 association or public health authority which has relied
    upon statements made on behalf of CTR in the conduct
18
19
    of -- strike that. In developing policy concerning
20
     smoking and health?
21
            I honestly don't know -- I know that the
22
    presentations made by tobacco industry spokespersons
23
    commonly cite the CTR. I don't believe that they use
24
    direct expressions from the CTR in those presentations.
page 406
page 407
     I am unaware of direct presentations by the CTR that
1
    have influenced those positions.
 3
         Q Let me ask you just one more question, or a
     couple more, and then we'll take a break for lunch.
 4
 5
         A Okay.
         Q If that's all right with you.
 6
 7
         A That would be wonderful.
         Q You're familiar with Dr. Benowitz, are you not?
 8
             I am.
9
         Α
            He's an authority in the field of smoking
10
         Q
11
    behavior; correct?
12
         A He's authority specifically in the area of
13 nicotine pharmacology and its impact on smoking
14 behavior, yes.
15
         Q If I were to tell you that Dr. Benowitz has
16
    testified that the pharmacological research done on
17
    nicotine under contract with Batco in the early 1960s
18
   was not novel research, would you have a basis as an
19 expert to say that he was wrong?
20
         A Without reviewing the context of that
21 statement, I wouldn't have a basis to say that he was
22 correct or incorrect.
         Q If I were to tell you that Dr. Benowitz has
23
24
     said that research would not have affected the
page 407
page 408
1
    conclusion reached by the Surgeon General in 1964 that
     smoking was a habit, again would you be in a position to
    say that he was wrong?
 3
         A I would agree with him on that, as the
 4
 5
    characterization that was used in the Surgeon General
 6
    report was based on the WHO criteria which required
 7
    social deviancy, and therefore, the pharmacological
    basis for nicotine addition would not have influenced
8
9
    that conclusion.
10
            I want to show you Dr. Benowitz' testimony in
     January of this year. This is his deposition in the
11
12
    National Asbestos Workers case at pages 131 and 132.
13
    And I've highlighted beginning at line 15 on 131 and
14
    going over the discussion regarding the Project Hippo
15
    work.
16
            Okay. I guess I --
17
            Do you want to wait until I give you a
18
     question?
19
            No, I'm just a little confused by some of the
20
    language here. But let me get through it.
21
         Q Okay.
22
         A Okay.
23
         Q Do you see where he says down at the bottom of
24 the first page he's asked whether the Hippo --
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page 408
page 409
1
         A Do you want me to hand this to you or do you
     want me to see it?
 3
            Why don't you just keep it.
 4
            Okay.
            Do you see where Dr. Benowitz is asked whether
 5
 6
    his opinions regarding the novelty of the Hippo research
7
    have changed? And he says they have not.
8
         A I believe the question you're referring to is,
9
    "So the notion that there was nothing new or anything
    novel in Project Hippo in 1963 would certainly be true
10
     in 1976; isn't that right"?
11
             That was the question I had some difficulty
12
13
    understanding.
14
             And Dr. Benowitz answered yes to that.
15
            Would you take a look at the prior page?
            I did.
16
17
          Q He's asked in the prior page whether he
18 regards -- whether he still is of the view that the
19 Project Hippo work was not novel when it was done in the
    early 1960s. Do you see that?
20
          A Okay. He says -- the question is, "Do you
21
2.2
    recall whether or not you agreed with Mr. Bernick that
23
    there wasn't any real new data or any new ideas that
     were reflected in the Project Hippo report? To use your
page 409
page 410
1
     words, that there was nothing novel?"
 2.
             Ms. McDevitt: "Objection."
              The witness: "I don't recall those words
 3
 4
     specifically, but I shouldn't ... I could have said
 5
     that."
              "Do you have any basis to disagree with that
 6
7
     sitting here today?"
              "No."
8
9
             Do you have any reason as an expert to disagree
10
     with Dr. Benowitz' testimony, as you have now recited
    it, on the novelty of the Hippo work?
11
12
            I don't believe that I have the context of
13
    Dr. Benowitz' testimony. I don't know what specifically
    he is referring to, and therefore, I'm not in a position
14
    to offer an opinion one way or the other as to whether I
15
16
    would agree with his interpretation of that.
17
          Q Have you made a review, Dr. Burns, of the
18
    literature prior to 1964 on the pharmacology of
19
    nicotine?
20
            I have generally reviewed that information. I
21
    have not conducted a specific review of that information
22
     for purposes of this trial or this deposition.
23
            What in the Hippo work that was done before
24
     1964, what in the Hippo work was novel; that is, did not
page 410
page 411
1
     appear in the then-existing literature on nicotine
 2
     pharmacology?
 3
            I would have to go back and review that body of
 4
    work to offer you a reasoned answer to that question.
    have not conducted a review of that work or of the
 5
 6
    literature at that time for purposes of answering that
 7
    question for this trial, and therefore, I don't have a
 8
    basis to answer your question.
 9
             MR. BERNICK: Let's take a break for lunch.
```

THE VIDEOGRAPHER: Off the record at 12:47 p.m. 10 11 (Lunch recess.) THE VIDEOGRAPHER: This marks the beginning of 12 13 Videotape Number 3 of Volume 2 in the deposition of 14 Dr. David Burns. We are back on the record at 1:28 p.m. 15 BY MR. BERNICK: Q Dr. Burns, in 1988 the Surgeon General issued a 16 17 report concluding that nicotine -- or that smoking is 18 addictive, and that nicotine in particular is addictive; 19 correct? 20 Α That's correct. Q In so concluding, the '88 report adopts the 21 criteria for dependence that were then in use through 2.2 organizations such as the APA; correct? 23 A Yes. Among others. 24 page 411 page 412 Would it be fair to say that the criteria that 1 were applied by the Surgeon General in '88 in concluding 3 that smoking was addictive are broad enough so that they would also require a finding that certain people who 5 consumed coffee are addicted to caffeine? A I think that there are aspects of those 6 7 descriptions that could be applied to coffee, that's 8 correct. 9 And in particular, Dr. Benowitz, 10 Dr. Honeyfield, and others have done the analysis and have concluded in writing that caffeine can be 11 addictive; true? 12 13 A That is correct. And that is consistent with 14 others who have done the same thing. Q In fact, isn't it true that Dr. Benowitz 15 16 petitioned the Food and Drug Administration to conduct 17 research into caffeine because, precisely because in certain circumstances caffeine could be addictive? 18 A I have no basis to know whether he has or has 19 20 not done that. 21 Q Not from the article that Dr. Benowitz has 22 published on caffeine? 23 A I've not read that article, no. 24 Q Are you an expert in the field of substance page 412 page 413 1 dependence beyond the work that you've done in 2 particular in connection with tobacco? 3 A I don't know what you mean. I have a substantial background in substance dependence as part 4 of my training in medicine. I have a particular 5 training in substance dependence because of my 6 7 background in intensive care medicine. And I have a 8 particular interest in one form of substance dependence 9 that I have pursued over the last 25 years, which is 10 tobacco. 11 I have at various points in time participated 12 in activities related to substance dependence in other areas, but it has principally been focused on tobacco. 13 Q You have -- would it be fair to say, I think, 14 15 you've testified previously that the term "addiction" 16 has different meanings to different people? 17 A I think that's true. 18 Q I'm sorry? 19 A I said, I think that's true. 20 Q Okay. And you've also described your own

definition of addiction, have you not? 21 22 A Yes, I have. 23 Q And just so that we can have a point of 24 reference, you've said that -- you use the term page 413 page 414 "addiction" for those things that interfere with 1 someone's ability to make choices about their future 3 behavior and that have a negative or detrimental effect? 4 A That's correct. Q With that definition of addiction, people who 5 overeat could fairly be described as being addicted to 6 7 eating; correct? A That's a much more complex scenario, because it 8 9 is not possible to simply stop eating. And the aspect 10 of the behavior that influences overweight has to do with both control of impulses and also influences of 11 12 hunger. And so it would be a much more complex thing to 13 describe simply with addiction. But certainly people 14 who are overweight where their overweight is detrimental 15 to their health and they are unable to alter behavior in 16 a way that reduces that when they are actively trying to do it, I think it would meet that definition, sure. 17 Q What? 18 19 Α It would meet that definition under those 20 circumstances, yes. Q People that continue to jog --21 A Let me make it clear. People would not say 22 they're addicted to food. They would say that they have 23 24 an eating disorder. page 414 page 415 Q But they would satisfy the definition of addiction that you have? A Well, they -- it's more complicated because of 3 the fact that you're not describing a use of a 4 5 substance, because everyone needs to eat. What you're 6 describing is an aberration in that behavior beyond the 7 level of ingestion of nutrition necessary to maintain 8 body weight. Therefore, it's a more complex description 9 than can be simply, "You're addicted to food." You are -- you have aspects of the behavior of eating that are 10 11 abnormal and consistent with a compulsive behavior, 12 which is the characteristic that has been associated 13 with addiction. 14 Q All I really want to know is that for people 15 who overeat and persistent overeat even when --16 overeating when they're told it's detrimental to their 17 health, would those people, or would they not, satisfy the definition of addiction that you have described? 18 19 A There are elements of that description which 20 they would satisfy. It's a more complex issue because 21 one cannot say they're addicted to food because everyone 22 23 People who gamble to the point that they lose 24 too much money and it affects their lifestyle, could it page 415 page 416 be said that those people are addicted to gambling? 1 2 A It can be said that those people are addicted 3 to gambling. It is said that those people are addicted 4 to gambling. In that setting one is talking about a behavior and an addiction to a behavioral response or

reaction to a certain circumstance rather than to a 6 7 pharmacologic agent. But one can characterize the resultant behavior with the same terminology, and many 8 9 people have. People who consistently drive cars too fast and 10 11 engage in reckless driving because it provides them with a thrill, is fast driving addictive to those people? 12 13 A I can't tell you whether it is or isn't. I've 14 not examined those -- the evidence on those folks enough 15 to know. I've not seen that described as an addiction. 16 I think it would be very difficult to qualify that as a medical illness, that certainly that would require any 17 kind of accommodation. 18 19 People who jog even after they've been told by 20 their doctors that it's hurting their joints, are they 21 addicted to jogging, within your definition? 22 A For people that compulsively jog when they know that it is injuring them and are unable to stop doing 23 that despite a volitional act on their part to stop, I page 416 page 417 think would meet that criteria. Again that's not something they're addicted to an agent, but rather to 2 3 the response to a behavior. 4 Dr. Benowitz has testified that he doesn't use 5 the word "addictive" before a jury because it's a loaded 6 term. Would you agree with that? 7 A I think that addiction carries with it a number of unattractive connotations. It also carries with it 8 9 in the general understanding of that term a strength of 10 the association or strength of the limitation of behavior, both of which are less with other terms that 11 12 have been used, such as dependence. Q Dr. Benowitz has also said that he does not 13 tell his patients, that is, his patients who are 14 smokers, that they are addicted because he doesn't think 15 16 it helps them. Would you agree with that? A Would I agree that he does that? 17 18 Q No, would you agree that telling smokers who 19 are being seen for smoking cessation, telling them they're addicted doesn't help? 21 A I think that most smokers acknowledge that they're addicted. My experience with people has been 22 23 that that is a term that they use about their own 24 behavior. That is a term that I have used in talking page 417 page 418 with patients. I don't believe that emphasizing the dependence, per se, is particularly helpful in 3 interacting with a patient. I think what you emphasize 4 are the tools necessary to break the dependence, or 5 break the addiction, rather than reinforcing whether or 6 not they're addicted. But I certainly have used that 7 term with patients. 8 Q Is Dr. Benowitz' approach a reasonable one, 9 which is to avoid using the label "addiction" in front of juries and to avoid using the label "addiction" in 10 11 dealing with smoker patients? A I think that that depends on the context in 12

which one is speaking to juries and patients. I would

patient who said, "Are cigarettes addicting?" "No." I

think that Dr. Benowitz would be unlikely to tell a

think he would say, "Yes, that they are addicting."

13

14

15

16

I think what he is saying is that he does not 17 18 feel it is terribly effective to focus on the presence of dependence, presence of the addiction as a principal 19 20 characteristic of interacting with people to get them to 21 auit. 22 And he uses the term "dependence," because that is the one that has been used in the general scientific 23 24 literature, particularly that scientific literature that page 418 page 419 1 Dr. Benowitz has published in. Both of those are reasonable positions. Q There are a number of people who do specific 3 scientific research in the area of smoking behavior; 4 5 correct? 6 A That's correct. 7 Q Are you familiar with people who are recognized experts within the field of smoking behavior? 8 9 A I know some of those people. 10 Q Is Carl Babbitt a recognized researcher in the field of smoking behavior, out of Germany? 11 A I can't tell you. He's not someone that I am 12 13 familiar with. 14 Q Have you taken a look at the literature, the 15 current literature to see what people who are 16 specialists in smoking behavior are saying today about 17 whether the proper term in describing smoking behavior is "habit" or whether the proper term is "addiction"? 18 Have you looked at that literature? 19 20 A I have looked at that literature. My 21 understanding is that the current use is to use the term 22 "dependence." 23 Q Okay. Are you aware, though -- have you taken a look to see in the literature whether there has been 24 page 419 page 420 discussion about the advisability of using the term 1 2 "addiction"? 3 A I'm sure that somewhere in the literature there 4 have been discussion of those issues. There was certainly a discussion of that issue around the '88 5 Surgeon General report. I'm not conversant with a 6 7 specific article. If you have something in mind that you want to show me, I'd be happy to look at it. 8 9 Q No, I'm really just kind of asking whether 10 you've kept up to date on what people in the field of 11 smoking behavior are saying is proper terminology in 12 talking about smoking behavior, whether it's dependence, or addiction, or habit? Have you just kept abreast of 13 14 the literature? 15 A I am generally conversant with that literature. 16 I'm not specifically conversant with a document that you 17 may or may not have. It is my understanding that the 18 people who work in that area currently use both the 19 terms "addiction" and "dependence." 20 Q Are there others who also use the term "habit"? A I am not specifically conversant with people 21 22 who use the term "habit" in an effort to characterize the relationships of ingestion of a drug in a compulsive 23 24 way that leads to alterations in their choices about page 420 page 421 subsequent behavior.

```
I'm going to show you an article that was
 2
     published by Dr. Babbett in 1998. And direct your
 3
     attention to a paragraph that I've highlighted for you.
 4
 5
     And ask you to read that for a minute.
 6
         A Do you have the article? I mean, you have
7
     given me page 83 and page 110 and 11 out of an article
     that is from page 83 to 115.
8
9
         Q Right, I've just given you an excerpt.
10
         A Okay. I have the excerpt.
11
         Q All you have is the excerpt, that's correct.
12
         A Okay. What would you like me to do with it?
13
         Q If you would just take a look at the paragraph
14 that I have marked there. And just read that over, if
15
    you would.
16
        A I have read the excerpts. Do you want me to
17
    hand it back? Okay.
18
         Q For the record, it says, quote, "Nevertheless,
19
   it is still a controversial issue as to whether smoking
20
    should be considered as an addiction rather than as a,
21
    perhaps, strong habit. This issue was discussed by
    several authors among other occasions in a special issue
22
     of Psychopharmacology in 1992 and also at the occasion
23
     of an international symposium on nicotine." And there's
24
page 421
page 422
1
    a 1994 citation.
 2
             "These discussions suffer not only from the
 3
    fact that the differences between heavy smoking and
    decompensated needs for alcohol, opiates or cocaine are
 4
 5
    profound. Another basic difficulty is there's no
 6
    generally-accepted definition of addiction."
 7
             Is it a reasonable statement for a scientist
 8
    within the field of smoking behavior today to make the
    statement that says that, "It is still a controversial
9
    issue as to whether smoking should be considered as an
10
     addiction rather than as a, perhaps, strong habit"?
11
12
         A I think that that is not consistent with the
13
    mainstream of scientific thought. I also think that the
14
    opening sentence of his article is also not factually
15
    accurate. The opening sentence of his article
    is that --
16
17
            I didn't ask you about the opening sentence of
    the article, Dr. Burns, did I?
18
19
         A You're asking me for my opinion as to whether
20
     this gentleman's positions are consistent with those of
21
    the scientific community.
22
         Q No, I asked you a very specific question, and
23
     you still haven't answered the specific question.
24
            Well, ask your question again.
page 422
page 423
1
             MR. BERNICK: May I have the question read
 2
    back?
 3
              (Record read as follows: "Is it a
 4
           reasonable statement for a scientist
 5
           within the field of smoking behavior
           today to make the statement that says
 6
 7
           that, 'It is still a controversial issue
 8
           as to whether smoking should be
9
           considered as an addiction rather than as
10
           a, perhaps, strong habit?'")
11
    BY MR. BERNICK:
12
         Q Can you answer that question, please?
```

I think that it is difficult for me to offer an 13 14 opinion about whether that is a reasonable statement in the absence of reviewing the discussion that he 15 16 describes prior to the statement "nevertheless." Okay? I think that that is not an accurate characterization of 17 18 current scientific thinking. And the limited amount of information I have on this article that you have given 19 20 me would lead me to believe that other statements in the 21 article, particularly the initial sentence, are also not 22 consistent with my understanding of the scientific 23 position at this point in time. 24 So in your view there is no -- it's not page 423 page 424 possible and reasonable for a scientist in the field of smoking behavior to say that there's still controversy 2 over whether smoking is an addiction or habit? It's no 3 longer controversial? 4 5 A I think, as I've said, that without reviewing 6 what this gentleman is referring to as his discussion of 7 the data and of the definitions he's choosing to use for addiction and habit, it is very difficult for me to 8 offer a position, okay, as to whether or not that is a 9 10 reasonable statement or not. 11 In science there are always issues that remain 12 controversial as you move forward. That is the nature 13 of science in a continued quest for information. As to whether or not the principal characteristics that I have 14 15 defined as addiction are generally accepted in the 16 scientific community as being consistent with the use of 17 the term "addiction" and whether those characteristics 18 relate to the nicotine in cigarettes, I think that those 19 issues are no longer controversial within the scientific 20 community. Without knowing the specifics of how this 2.1 22 gentleman is choosing to use the word "habit" as opposed 23 to "addiction," then it makes it very difficult for me to offer an opinion as to whether he is expressing a 24 page 424 page 425 reasonable position or not. 1 MR. SCHROEDER: Mark that. 2 BY MR. BERNICK: 3 4 Q Would you agree that it is controversial 5 today -- strike that. 6 Would you agree that there is no generally 7 accepted definition of addiction today? 8 A No, I would not. 9 Would you agree that there is controversy, 10 given what Dr. Benowitz testified to, as to whether 11 smoking should be described as addictive versus being 12 described as dependence producing? 13 A I think that there is a difference in choice of 14 use of those terms amongst the scientific community with 15 the preference of those people who are working in the field being for the use of the term "dependence." 16 Q Dr. Burns, Dr. Benowitz also has stated --17 18 could you hand back the first part of that article to me, please? Thank you. 19 20 Dr. Benowitz has also said what matters is not 21 the label that is applied to smoking behavior, that is, 22 whether it's addictive or not. What matters is 23 conveying the fact that it can be difficult to quit

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page 425
page 426
         A I would agree, depending on the context in
    which it was written, that that is important. I believe
 3
     it is also important to define whether or not it meets
    the characteristics of addiction or characteristics of
 5
    dependence for a variety of informational and public
 6
    policy purposes. But in general, I think that the
 7
    principal -- I would agree with Dr. Benowitz that the
 8
    principal issue is whether -- is not the term that is
 9
    used but the impact of that ingestion on the behavior of
10
    the individual.
         Q In other words, what's important to convey to
11
12
    people is not necessarily the label, but the ultimate
    fact that it can be very difficult to quit smoking;
13
14 would you agree with that?
15
         A Well, I think that it's slightly beyond that.
16 It's important to convey to them that the reason why it
17
    is difficult for them to quit has to do with their need
18
    to compulsively ingest a given substance, and that that
19
     substance is a principal part of the reason why they're
    having difficulty quitting.
20
         Q And that substance being nicotine?
21
22
         A Nicotine, that's correct.
23
         Q And recognizing that the label that's used in
    talking about smoking behavior is much less important
page 426
page 427
1
    than the operative fact that people have a hard time
    quitting because of nicotine; is that fair?
 2
         A The behavior consequence is clearly the most
 3
 4
    significant issue. The choice of a word to communicate
    that is dependent on the need to communicate accurately
 5
    the reality and the strength of the change in behavior
 6
 7
     that accrues from repetitive injection of nicotine
    through cigarettes. And that, therefore, the choice of
9
    the term that is used is an effort to communicate
10 accurately what the consequences of that regular
11 ingestion of nicotine through cigarettes will be or is.
12
         Q And would you agree that in Dr. Benowitz' view
13 it is less productive to use the term "addiction" and
14
    more productive to use the word "dependence"?
15
         A No, I would not agree with that as a global
16
   statement. I think Dr. Benowitz may have expressed that
17
    in certain contexts. Dr. Benowitz was also one of the
18 editors of the Surgeon General's report where they chose
19 to use the word "addiction." So I would expect that his
20 considerations of those issues would not be as global as
21
    your question would imply.
22
    Q Dr. Benowitz has also testified that the
23 essence of the definition of "addiction" is "difficult
24
    to quit." Would you agree with that?
page 427
page 428
            Yes. I think that the most important
1
     characteristic of that definition is the interference
 3
     with the choice to stop smoking.
        Q And isn't it true that that property of
 4
 5
    smoking, that is, the addictive effect of smoking in the
     sense that it's hard for people to quit, has been known
 6
 7
     to the scientific and medical community prior to 1964?
         A I think that it has been known for some time
```

smoking. Would you agree with that?

24

9 prior to 1964 that people have difficulty stopping smoking, that is correct. 10 11 Q Indeed, isn't it true that according to 12 Dr. Honeyfield -- he's another specialist in this area, 13 is he not? 14 Yes, he is. Α I want to read from you -- read to you a 15 16 statement that he makes in an article that he published 17 in 1988, where he said, "Centuries ago the answer was 18 known tobacco can addict those people who sample it and 19 it can addict with the power of substances such as 20 alcohol and opium." Would you agree with that statement? 2.1 22 Would I agree with the statement that nicotine 23 can addict and that that has been -- that people have known for quite some time that use of tobacco creates a 24 page 428 page 429 difficulty in stopping the use of tobacco? Yes, I would agree with both of those statements. I would disagree, however, with the statement 3 4 that the use of that term in relation to the 5 pharmacology of nicotine, okay, has been well understood 6 for a very long period of time. 7 As to this statement, I'll read it to you 8 again, Dr. Honeyfield says, the statement that's right 9 in front of you, that for centuries it's been known -the addictive qualities of smoking or tobacco have been 10 11 known. Would you agree with that? 12 A I would agree with the statement that people 13 have known that the regular ingestion of tobacco leads to a circumstance where it is difficult to stop that 14 15 regular ingestion. I would disagree that people have 16 known that the characteristic that drives that is the pharmacologic response and physiologic changes that 17 accrue due to the ingestion of nicotine that we 18 19 currently characterize with the term "addiction." 20 So I would agree that people understood the 21 consequences relative to behavior. I would disagree 22 that they knew the specifics of the use of the term 23 "addiction" relative to the ingestion of the nicotine 24 and tobacco. page 429 page 430 1 MR. SCHROEDER: Would you mark that one, 2 please? 3 BY MR. BERNICK: 4 Q And with respect to just practical wisdom on 5 quitting smoking, practical wisdom on quitting smoking that is reflected in the term "addiction," the practical 6 7 wisdom is the difficulty of quitting; correct? We've 8 already been through this; right? 9 The practical wisdom being what? 10 Q The practical wisdom that is embedded in the 11 idea that smoking addictive is that it can be very hard to quit; correct? 12 The practical reason, as I understand it, for 13 14 the use of that term by the general population is that it is a drug ingested that makes it very difficult to 15 16 stop ingesting the drug. That's how most people 17 understand that. They currently understand that when 18 they're addicted, they're addicted to the drug nicotine. 19 Q Isn't it true that the difficulty of quitting

20 smoking has been written about in the lay press for 21 literally centuries? 22 A Yes, that's true. 23 Q Isn't it also true that the idea that people 24 who smoke are smoking for nicotine has also been page 430 page 431 published in the lay press going back into the early 1 part of this century? 2. 3 A There has been a publication of that 4 information for a substantial period of time, that's 5 Q Isn't it also true that beginning in the early 6 7 1940s -- actually, beginning even before the 1940s, 8 there were scientific publications where scientists said 9 that nicotine was the most important factor in the 10 smoking experience? 11 A I think that that's also true. 12 Q And isn't it true that by 1942 scientists were 13 publishing articles that said that not only is nicotine important for the smoking experience, but people smoke 14 for nicotine, like drug users take drugs for the 15 pharmacological effects of drugs; isn't that true? 16 17 A There were individual articles that presented 18 that position. 19 Q And in point of fact, the tobacco industry 20 sponsored articles that were published even before 1964 21 which said that smoking is addictive; true? 22 A I don't have a specific instance in mind. I 23 don't know what you're referring to. 24 Q Did you ever look to see whether -- what page 431 page 432 research the tobacco industry sponsored about the 1 addictive effects of nicotine prior to 1964? A I have reviewed some of that literature. 3 4 don't know specifically what you're referring to. 5 you have a specific citation, I would be happy to look at it and offer my opinion on it. 6 7 Q Is it true that if the criteria applied in the 8 1964 Surgeon General's report for determining whether 9 smoking was addictive or habituating were applied today based upon today's scientific knowledge, that the answer 10 11 would still be that smoking is a habit and not an 12 addiction? 13 A Those criteria applied today would lead to the 14 conclusion that it was a habit. The reason for that is 15 that the criteria used at that time by the Surgeon 16 General's report required evidence of social deviancy in 17 order to differentiate between a habit and an addiction. 18 And there is not evidence of social deviancy, criminal 19 behavior, robberies, assaults and other kinds of 20 activities in relation to cigarette smoking. That is a 21 criteria that was disregarded shortly thereafter. 22 One of the other criteria that was applied in 23 1964 were the intoxicating qualities; correct? 24 A That's correct. page 432 page 433 1 Q And isn't it true that both then and now there 2 is not evidence that nicotine is intoxicating? A I think that depends on your definition of the 4 term "intoxicating." If you are using the term

5 "intoxicating" in its more traditional sense of interfering with judgment, there is no evidence that 6 nicotine is intoxicating. If you use it in a broader 7 sense of having a psychoactive effect, there is evidence that nicotine does have a psychoactive effect. 9 Q How was the Surgeon General in 1964 using the 10 term "intoxicating"? 11 12 A I believe he was using it in terms of it 13 creating a euphoric effect that interfered with 14 judgment. And again today -- based on today's science, 15 16 again that criteria would not be satisfied by smoking; 17 correct? That's correct. 18 19 The Surgeon General also talked about 20 physiological withdrawal being another criteria for addiction in 1964; true? 21 22 A That's correct. 23 Q And again, by today's science that criteria 24 would also not be satisfied by smoking? page 433 page 434 I don't believe that that is true. I think 1 Α 2. that there is evidence of physiologic withdrawal from nicotine that would meet that criteria. 3 4 Q Is there any evidence that you're aware of, in 5 the sense scientific studies -- are aware of any scientific studies which demonstrate that people are 6 7 more able to quit smoking once they know that cigarette 8 smoking is addictive? 9 A I'm not aware of a study that has investigated 10 that point one way or the other. 11 Q Are you aware of a study which has investigated 12 whether people are less apt to start smoking if they heard that smoking is addictive? 13 A I'm not aware of a study that has examined that 14 particular issue in isolation. It certainly is an issue 15 that is of concern in presenting information to 16 17 adolescents. But I'm not aware of a study that has 18 examined the effect of providing that information in 19 isolation of the other information that is provided to 20 adolescents in an effort to help them resist starting to 21 smoke. Are you aware of the degree -- strike that. 22 Are you aware of any studies which establish 23 24 that people today are better informed about the page 434 page 435 1 difficulty of quitting smoking than they were at any point in time in the past? 3 A I'm not sure what you're saying. 4 Q I'll withdraw the question and make it clearer. 5 A Okay. 6 Q We've talked about the fact that the practical 7 wisdom about the term "addiction" applied to smoking is 8 the difficulty of quitting? 9 A Yes. 10 And all I'm asking is, have any studies been done to determine whether people today are more or less 11 12 aware of the fact that it's tough to quit smoking than 13 they have been in the past? 14 A It is my understanding that there have been 15 survey that has been done that has shown an increase in

the frequency in which people report positive responses 16 17 as to whether smoking is addictive, and also positive 18 responses on the part of smokers as to whether they're 19 addicted. 20 I'm not aware of an increase in survey work 21 that has shown, or a change in survey responses to the question, "Is it difficult to stop smoking?" 22 23 Let me ask you a few questions about another 24 subject, and I will pass the baton to somebody else. page 435 page 436 1 Not, of course, leaving you free to go. 2. Α I had not --We wouldn't want to disappoint your expectation 3 4 that you're chained to --5 A I have not expected --6 Q -- your chair for the rest of the day. 7 A -- that that would happen. 8 All right. Are you aware, Dr. Burns -- you've testified previously -- what did I do with that? You 9 testified previously about the -- whether the FTC 10 11 delivery method had the effect of deceiving smokers about their exposure to smoke from low delivery 12 13 cigarettes; do you recall that? 14 I don't recall testifying with that specific 15 characterization. I certainly have testified before on 16 the disease consequences of different brands of cigarettes, and on measurement of tar and nicotine of 17 18 cigarettes of different manufacturing types. 19 But more specifically, I think you've testified 20 about whether people who smoke understand what the FTC 21 delivery figures mean; that is, the tar and nicotine 22 figures mean? 23 A I have testified on the issue of what people 24 understand from both those figures and also from the page 436 page 437 1 characterization by brand of terms such as "light" and "utralight." 2. 3 Okay. Are you aware of any new studies that have been done to determine the degree to which the FTC 4 method provides guidance on how much smoke the smoker 5 actually takes in from these different brands? Is there 6 7 any new science out there on this? 8 A I'm not sure what you're saying. From what 9 point in time would you like me to characterize the --Since the fall of 1998. 10 11 There is a substantial body of work that we are 12 currently working on which has been presented to the 13 Institute of Medicine and was part of a deposition in 14 the Little case, that has to do with the relationship 15 between disease consequences, specifically lung cancer, and various brands of cigarette characterized by tar. 16 17 It also has to do with changes in number of cigarettes 18 smoked per day, based on changes in brand proportional to the change in nicotine. 19 20 And there is also data on the use of numbers of 21 cigarettes in California based on the tar and nicotine 22 rating of those cigarettes. 23 In addition, there is work that is in process to collect new survey data by the Robert Wood Johnson 24 page 437 page 438

foundation on the specific issues of what people 1 understand about low tar and nicotine cigarettes. 2. But is there any -- is there any new studies 3 4 that have been done on what the actual deliveries to the person are versus the machine delivery? 5 A I'm not sure what specifically you're asking. 6 7 Certainly the data from California on the number of 8 cigarettes smoked per day relative to the nicotine yield 9 is a substantively new contribution to the area of how 10 much people ingest with brands of cigarettes with 11 different tar and nicotine. 12 Who published that study? A I am doing that work in conjunction with people 13 14 in my office. We have presented that work at the 15 Institute of Medicine. It has not yet been published. 16 Q Let's just focus on published work. Is there 17 any more recent published work on the question of how actual smoking delivery compares to the machine 18 19 20 I would have to go back and look as to whether 21 things have been specifically published from the fall of 22 1988, is what you're asking me? 23 Q Right. 24 Α There may be additional studies that have been page 438 page 439 published since that time. I don't have that date fixed 1 firmly enough in my head to tell you whether the studies 2. that I've reviewed are before or after that date. 3 Q Have you written an article or co-authored an 4 5 article with Mr. Penny on the question of whether the FTC method of measuring deliveries is -- gives 6 7 meaningful information? Actually, it's an editorial. 8 A Is that what you were referring to by the date 9 1998? No. Since 1998. That's what I was asking. 10 11 Okay. Α 12 You were involved in writing an editorial, were 0 13 you not? 14 A I was involved in writing an editorial on an 15 article that was published in the Journal of the 16 National Cancer Institute. If that's what you're referring to, yes, I believe that that data, as I 17 18 recall, is after the 1998 date. 19 Q What's the data that was published in the -- is 20 it Journal of the National Cancer Institute? 21 A Yes. 22 Q What was the data that was published about 23 smoke deliveries? 24 A As I recall, and it would obviously help to page 439 page 440 review the article again, it was an article that 1 examined the machine-measured yields of low tar and 2 3 nicotine and higher tar and nicotine cigarettes when the 4 machine smoking parameters were set based on the actual observed smoking parameters of individuals who had 5 6 smoked those cigarettes. 7 Q Who are the -- who are the researchers in that 8 work? A I don't remember the specific names from 9 10 American Health Foundation. You got the lead one mentioned here is 11

```
Djordjevic?
12
13
     A Right.
14
         Q Who is that?
15
         A He's an individual at the American Health
16 Foundation, as far as I understand. I don't know him
17
    personally, or her personally.
         Q You say that that study, quote, "Elegantly
18
19
    demonstrates that the Federal Trade Commission method of
20 testing cigarettes for tar and nicotine provides tobacco
21 companies the opportunity to mislead their customers."
22
        A That is what was written in the editorial, that
23
     is correct.
         Q You were one of the authors of that editorial;
2.4
page 440
page 441
1 correct?
2
     A I was one of the signatories to that editorial,
3 that is correct.
         Q Apart from whether you believe that the
 5
    Djordjevic, that's D-j-o-r-d-j-e-v-i-c, that that study
    was elegant or not, is Djordjevic a recognized
 6
    researcher in this area?
 7
         A I believe that he is, he or she is someone who
8
9
    has done work in this area. I don't have a specific
10 knowledge of their CV.
11
         Q Did you take a look at the article published by
12 Djordjevic in the Journal of the National Cancer
13 Institute to see whether it applied sound methods and
14 reached sound conclusions before you signed on to this
   editorial?
15
16
         A Yes.
         Q What did you find out about the situation?
17
18
         A I thought it was a credible article.
         Q Credible article. I didn't really think I was
19
20 asking about that. I asked whether the article applied
21 sound methods and reached sound conclusions about the
22
    data that it gathered?
23
         A I'm sorry, I had thought that's what was the
24
    definition of credible. As far as I understand, it
page 441
page 442
    applied sound methods and reached sound conclusions.
1
     Q And this is the Djordjevic article that was
 2
 3
     just published in the Journal of the National Cancer
 4
    Institute?
 5
        A Yes.
 6
         Q Okay.
7
             (Discussion off the record.)
8
             (Deposition Exhibit 6 marked.)
9
    BY MR. BERNICK:
10
     Q Is Exhibit 6 a copy of the Djordjevic article
11 that you reviewed and that you've just been referring to
12
    as the subject of commentary, the editorial that you
13
    helped write?
14
        Α
           As far as I can determine, this is a copy of
15
    that article.
         Q And did you -- before you again -- this is a
16
17
    fairly strong statement that you made in the editorial,
18
    that, "The article elegantly demonstrates that the FTC
19
    method provides tobacco companies the opportunity to
20 mislead their customers." It's a fairly strong
21 statement, isn't it, Dr. Burns?
22
        A I think that is a strong statement of what is a
```

```
23
     generally-accepted fact at this point in time.
24
    Q Well, did you -- before you wrote the editorial
page 442
page 443
     that you did this year in the JNCI, did you -- I don't
1
     see anywhere in the editorial where you state that there
     are any limitations or qualifications in the work that
 3
     Djordjevic did and published in Exhibit 6?
 5
            The fact that one in an editorial doesn't
     describe every aspect, positive, negative, strength,
 6
 7
    weakness, limitation, complete citations of a given
    article, does not necessarily mean that one is either
 8
     endorsing that or is implying that there are no
 9
     limitations. The --
10
         Q Well --
11
12
         A -- purpose of an editorial is to focus on an
    aspect of the article that is particularly significant,
13
    and to help the readers understand the significance of
14
15
    the article. It is not intended usually to be a
16
     detailed criticism of all aspects of the article.
            Well, before you signed on to the editorial,
17
    did you -- were there, in fact, limitations or
18
19
    qualifications on the quality of the research that
20
    Djordjevic did as published in Exhibit 6?
21
         A As I've testified earlier in this deposition, I
22
    know of no scientific article, epidemiologic or
23
     otherwise, that does not have limitations. Everything
     by definition is finite and has limits.
24
page 443
page 444
              If you're asking me about specific pieces of
1
     methodology that you would like me to comment on, I'd be
 2
    happy to do that. I'm also happy to acknowledge that
    this piece of work is not a complete, total description
 4
     of everything that is ever going to need to be known on
 5
    this topic. It is a piece of work that describes
 6
 7
    specific observations under specific circumstances. By
 8
    definition of everything that we understand in science,
9
    that, of course, places limits on the information
10
    available and the interpretation of that.
11
         Q Are you aware of any erroneous conclusions that
12
    are reached by Djordjevic in his article, Exhibit 6?
13
         A I haven't reviewed the article specifically to
14
    attest to whether or not I agree with every single
    statement contained in the article. If you would like
15
16
    to ask me about a specific statement, I would be
17
    perfectly happy to give you my opinion on that. But as
18 I sit here from memory, I'm not capable of recalling
19
     every sentence that was written in the article.
20
         Q Do you recall what it is that Djordjevic found
21
     about the total exposure to smoke of the groups that he
22
    was studying? That's a poor question. I'll withdraw.
23
         A Yes, it's a poor question.
24
          Q He was taking a look at people who smoked
page 444
page 445
    medium tar cigarettes and low tar cigarettes; is that
1
 2
    correct?
 3
         A That's correct.
 4
         Q Do you recall what he concluded about the level
 5
     of the smoke exposure as between the two groups?
 6
        A He has a series of very specific conclusions
     that he reached. And they relate to both the ingestion
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of tar and the ingestion of some of the individual 8 chemical constituents. And his conclusion is that the 9 10 FTC protocol underestimates nicotine in carcinogen doses 11 to smoker and overestimates the proportional benefit of 12 low yield cigarette. 13 Do you agree or disagree with that? Agree with that statement. 14 Α 15 Okay. Go on. 16 A "Thus, FTC-based nicotine medication doses 17 prescribed/recommended for smoking cessation may need to 18 be reassessed." Q Do you see where he makes a statement -- if 19 you'll hand me, I'll show you more precisely. I'll mark 20 it with a dot. 21 22 A Okay. 23 Q Where he reaches the conclusion that smokers of 24 medium yield cigarettes compared with smokers of low page 445 page 446 1 yield cigarettes received higher doses of all components? 3 That is what he concluded, that's correct. 4 0 Do you have any reason to question that 5 conclusion? 6 A No. I think that the conclusion is 7 substantiated by the data that he presented. 8 Q I want you to direct your attention, if you would, to --9 A Perhaps I should caution you, however, so I 10 11 don't leave you in the lurch. That is not a statement 12 that says people who switch from one type to another will receive lower doses. That is simply a statement 13 14 that the population of people who use these products, okay, is a different population of individuals who 15 ingest less nicotine and, correspondingly, ingest less 16 17 18 Do you know whether or not the population that 19 he is looking at includes switchers? 20 A I am sure that the population he looked at 21 includes people who have switched. The population he 22 looked at, as I recall, and if we need to explore the 23 issue in detail, we should go back and look at the article, was individuals who were using those brands 24 page 446 page 447 stably, rather than individuals who were specifically 1 switching from one brand to another. 2 3 Q But if you wanted to see whether switching 4 down, that is, switching from a higher delivery cigarette to a lower delivery cigarette, ended up 5 6 reducing total smoke intake, you want to look at that 7 reliably, you'd have to take a look at the results of 8 the switching over a long period of time, would you not? 9 A In order to examine that question, one would 10 have to examine that in a variety of contexts. It's been a complex question to examine. We know that there 11 are differences in the use of the first cigarette, that 12 13 do not persist over multiple cigarettes for the next days. We know that there are differences that are 14 15 present in the first days that are not present over a 16 longer interval. 17 We know there are differences that are observed 18 when you ask people to switch that are not observed in

people who spontaneously switch. We know there are 19 20 differences in people who switch because they are trying 21 to quit, in comparison to individuals who switch without 22 an effort to quit. There's a variety of differences that need to 23 24 be accounted for in examining the question of to what page 447 page 448 1 the actual effect is when one switches from one brand or 2 the other. 3 Perhaps we could take a short biologic break. I will be back in a minute or two. 4 MR. BERNICK: Okay. 5 THE VIDEOGRAPHER: Off the record at 2:19 p.m. 6 7 (Recess.) 8 THE VIDEOGRAPHER: We are back on the record at 9 2:23 p.m. 10 BY MR. BERNICK: 11 O Dr. Burns, the FTC has regulated cigarette 12 advertising since the late 1930s; correct? A I'm not sure exactly what you're saying. The 13 14 FTC is certainly responsible for investigating false and misleading advertising, and certainly has interacted 15 16 with the tobacco companies episodically over that period 17 of time on various issues. They do not, in fact, 18 actually regulate the content, quality or any other 19 aspect of the tobacco advising, per se, independent of 20 its false and misleading nature. Q That's the point, is the FTC has got the power 21 22 of the federal government to monitor cigarette 23 advertising. And if they feel that the cigarette advertising is false or deceptive, they have the 24 page 448 page 449 1 authority to act to cause that advertising to cease; correct? 3 A That is correct. 4 And they have had that authority since the 0 5 1930s; correct? 6 A I don't know when the FTC act was passed. 7 Q Isn't it true that in 1955 the FTC actually issued specific guidelines pursuant to its power to 8 regulate cigarette advertising to ensure that it wasn't 9 10 deceptive? 11 A I'm not sure what you're specifically referring 12 to. They had developed proposed guidelines. I'm not 13 aware if those guidelines were ever implemented. 14 Q You're not aware of any quidelines the FTC has 15 ever issued regarding claims that are made with regard 16 to the properties of cigarettes in advertising of 17 guidelines? 18 A No. They have issued a variety of guidelines. 19 I'm not aware of the specific ones you're referring to. 20 My understanding was that during the early stages of the 21 FTC's consideration of this issue they were proposing 22 fairly stringent guidelines on tobacco industry advertising, and that the tobacco industry's response 23 24 was to develop voluntary guidelines. But if that is not page 449 page 450 1 the topic that you are referring to, perhaps you could explain it to me. 3 Q Do you recall in the early 1950s the cigarette

companies began to put filters on their cigarettes and to make claims about the tar and nicotine deliveries of the new cigarettes?

- A That's correct.
- Do you recall that in about 1955 the FTC issued regulations on what the industry could claim with respect to tar and nicotine delivery?
 - Yes, they did.
- Do you recall that during the latter part of the 1950s the FTC took action to stop the cigarette companies from disclosing tar and nicotine deliveries on their packages?
- A They prohibited, as I recall, the disclosure of tar and nicotine on the packages because they felt that that was a deceptive form of advertising at that time.
- Q And do you recall also that in about the mid 1960s the FTC changed its mind and decided that it would be permissible for the cigarette companies to put the tar and nicotine deliveries on their packages provided that those deliveries were measured in accordance with a method that have been developed by the FTC?

page 450 page 451

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- They did, indeed, allow that. I'm not sure Α changing their mind is the appropriate characterization. They felt that it was consistent with what the scientific community was thinking at that point in time, that a method that allowed a comparison between cigarettes in terms of the likely delivery of those cigarettes was something that might be useful to consumers in terms of information that they would use to choose between cigarettes.
- Q And the protocol that they required be followed, that is, the method that they required be followed in measuring tar and nicotine deliveries, was a method that the government itself had developed; correct?
- My understanding is that it was developed in conjunction with tobacco -- scientists and tobacco industry scientists, and had been modified from previous methods rather than invented out of whole cloth. But it certainly was one that was specified by the government, ves.
- Do you recall that at about the time that the FTC determined in the mid 1960s that it would be permissible to disclose tar and nicotine deliveries, that the public health community affirmatively endorsed page 451

page 452

- the idea that the tar and nicotine deliveries should be stated by the tobacco companies?
- A The public health community on multiple occasions has endorsed the fact, or endorsed the proposition that reducing the amount of smoke, or tar as a measure of that smoke, delivered to people would be something that would be a positive health outcome.
- Q My precise question, though, was whether, in 8 9 fact, the public health community in the mid 1960s formally endorsed the idea that the cigarette companies 10 11 should disclose the tar and nicotine deliveries of their 12 cigarettes?
- 13 A They formally endorsed the concept that the 14 cigarette companies would disclose the delivery of tar

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and nicotine to people who smoked those cigarettes.
15
16
     Q In fact --
17
         A And they endorsed the erroneous concept, as it
18 turns out, that the FTC method would distinguish that.
         Q Dr. Burns, in fact, wasn't it true that it was
19
20 the public health community that actually wrote the FTC
21
    and urged them to allow the cigarette companies to
22
    disclose tar and nicotine deliveries?
         A Since there is no public health community,
23
24
    per se, as an a organized group --
page 452
page 453
         Q The American Cancer Society.
1
            The American cancer Society and other
 2
 3
    individuals, as well as other organizations, clearly
 4
     endorsed the FTC allowing that information to be present
    on advertising and endorsed the FTC method as a means of
 5
 6
    measuring that.
 7
         Q Isn't it true that by the end of the 1960s,
8
    both the FTC and public health organizations, such as
9
    the American Cancer Society, not only wanted the
10
    cigarette companies to disclose the tar and nicotine
    deliveries on the packages, but they wanted the
11
12
    companies to be required to state the tar and nicotine
13
    deliveries in cigarette advertising?
14
         A I believe that that is probably true. I don't
15 have a specific recall of that detail.
         Q Do you recall that ultimately it became
16
    mandatory, that is, Congress passed a law that required
17
18
    the tobacco companies to disclose tar and nicotine
19
    deliveries per the FTC method in all of its advertising?
20
         A Yes, I believe that's true. I don't recall
21 specifically that it was a law, but I do know that it
22
    was mandated.
23
         Q That's remained in place ever since; correct?
24
         A I believe so.
page 453
page 454
1
         Q Has it also remained a requirement on the
 2
    tobacco companies that they disclose the tar and
    nicotine deliveries on all the packages?
 4
         A I don't know the details of the requirements
    for the packages. My recollection is that it was
 5
    required -- that it is on some packages, but not on
 6
    others. But I don't have a specific recall of the
 7
 8
    details of that regulation.
9
         Q Isn't it also true that even today, if the --
10 if and when the tobacco industry has to make disclosures
11 of tar and nicotine deliveries to the consumer, that
12
   it's required to use the FTC method of delivery as a
13
    meter of law?
14
         A Well, your question includes an assumption that
15
    is erroneous. The tobacco companies do not report
16
    delivery to consumers. They report delivery to a
17
    machine. And that is the genesis of the concern. That
18
    what the public health community was, indeed, interested
    in was the delivery to the consumers. What is being
19
20
    reported is the delivery to the machine, that no longer
21
    reflects the delivery even relatively to the consumer.
22
             MR. SCHROEDER: Mark that.
23
     BY MR. BERNICK:
        Q We'll get to that in a moment. But my question
24
page 454
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1 really was a very different one. A Your question included that assumption. 3 Q It didn't make any assumption. A I'm sorry, but that -- I think that was there. 4 5 I don't want to debate the issue. I'll just ask another question, Dr. Burns. 6 7 Isn't it true that where the tobacco industry 8 is required to disclose tar and nicotine deliveries, 9 that is, in its advertising at the very least, and 10 you're unsure about the packages where it's required to disclose the tar and nicotine deliveries, that it must 11 disclose those deliveries as measured by the FTC method? 12 A Yes, the tar and nicotine delivery recorded on 13 14 the advertising must be that tar and nicotine measured 15 in machine delivery with FTC parameters. 16 Isn't it true that ever since -- even before the FTC announced the requirement that its machine 17 18 delivery method be used by the industry, even before 19 that, the FTC was specifically told that its machine delivery method did not necessarily reflect smoke 20 21 exposure to the smoker? A The FTC was told that it did not reflect the 22 23 exposure to individual smokers. It was also told the 24 differences between cigarettes with the FTC method were page 455 page 456 likely to reflect differences in consumption of 1 individual smokers that used those brands. So while the 3 absolute measurement did not reflect the dose, that the 4 information between cigarettes was a piece of information that would have been of use to the consumer. 5 6 Is there anyplace in any submission made by the 7 tobacco industry to the FTC where the representation is made that the FTC method, in fact, will reflect the 8 relative ranking of cigarettes as the consumer is 9 10 exposed to smoke from those cigarettes? 11 A I don't know that the specific wording is 12 contained in the tobacco industry submission. I am 13 aware that the reason the FTC allowed that label to be placed on the cigarettes was that the public health 14 community at that time believed that while the absolute 15 level did not correspond to what people would ingest, 16 17 that the relative levels across cigarettes as measured 18 by the FTC method by machine would translate into 19 relative differences across those brands in the amount ingested by smokers, and therefore, that would provide 20 21 information that would be of use to the individual 22 smoker in altering their disease risk. 23 Q Are you --24 That assumption has turned out to be page 456 page 457 inaccurate. But that is what the belief was that 1 supported the use of that information in advertising. 3 Q Did the tobacco industry ever make that 4 representation to the FTC or to any other governmental 5 authority? A I don't know specifically whether the tobacco 6 7 industry ever made that representation. The representations that I have seen from the tobacco 8 9 industry state that the FTC yield does not reflect the 10 individual ingestion by the smoker.

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In fact, isn't it true that the tobacco
11
12
     industry has both in published scientific articles and
13
    in actual litigation involving the government
14
     specifically stated that the FTC measurements may be
15
    misleading to the consumer?
16
         A I wouldn't be surprised that they have made
17
    that statement. That is a statement that has been
18
    accepted by the FTC and accepted by the public health
    community within the context of the decisions they made
19
20
    for the purposes that I previously described.
21
         Q Isn't it also true that -- strike that.
22
             You in your testimony in the past have from
    time to time attacked certain advertising or ads that
23
24
    were used by the tobacco industry to advertise low
page 457
page 458
    delivery cigarettes; true?
1
        A That's a very broad statement. I certainly
 3 have been critical of tobacco industry advertising
 4
    practices relative to low tar and nicotine cigarettes,
 5
            Are you aware of any ad, any low tar delivery
 6
 7
    ad that has been attacked by the FTC as being misleading
8
    since 1960?
9
         A I would have to go back and look specifically
10 at the FTC actions. I can't tell you specifically
    whether they have attacked it or not.
11
            In fact, they did attack the Barclay ads, did
12
13 they not?
14
         A They did. That was on a different issue. But,
15 yes, they did attack the Barclay ads.
         Q No, they attacked the Barclay, if you recall,
16
17 see if this refreshes your recollection, they attacked
18 Barclay ads because they represented they only delivered
    one milligram of tar, and the FTC felt that given the
19
    unique design of the filter, the filter actually
20
21
    delivered -- the cigarette actually delivered more tar
    than that. Do you recall that?
22
23
        A I'm familiar with that. I'm familiar with the
24 fact that the ventilation in the Barclay was of a
page 458
page 459
    different character than the ventilation for other ultra
 1
    low or low yield star cigarettes, and that that was a
 3
    matter of controversy to the tobacco companies, even
 4
    though the tobacco companies acknowledged in their
    submissions that ventilation was the principal method by
 5
    which tar was reduced.
 6
 7
         Q You're going on talking about a bunch of stuff
8
    that has nothing to do with the question, Dr. Burns.
9
         A I'm just trying to be responsive to your
10
    question.
11
            MR. BERNICK: Just read the question back,
12 please.
13
             (Record read.)
14 BY MR. BERNICK:
15
     Q It's relatively simple question, Dr. Burns. Do
16
    you recall that?
17
         A I recall.
18
         Q Good. Are you aware of any other cigarette ad
19 that has ever been attacked by the FTC for
20 misrepresenting the deliveries of cigarettes to the
21
    consumer, for misrepresenting the safety of low delivery
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22 cigarettes, or any other property of low delivery 23 cigarettes? 24 A My understanding was that there was -- that was page 459 page 460 the basis of the restrictions early on. I'm not sure 1 exactly the date of those restrictions. I believe you 3 asked me to characterize it from 19 --Q 1960. 4 5 A -- 60 on. I don't know specifically when the FTC ruling was in relation to that date. I'm assuming 6 7 from your facial expression that it was after that, that the ruling preceded that 1960 date. I'm not familiar 8 with another advertising investigation by the FTC 9 10 specifically directed at the delivery -- the advertised 11 delivery of cigarettes relative to what the consumer would get. 12 13 Q A time came when people began to do research 14 into what was called compensation; correct? 15 A That's correct. What compensation means is that people who 16 17 switch cigarettes from one delivery to another may change their smoking behavior because they're getting 18 19 less of what they want out of cigarette, be that 20 nicotine, tar, or some other property; correct? 21 A Well, that's a cumbersome definition. The 22 definition that I think makes some sense is that people 23 change the way they use a cigarette with a different 24 yield in order to preserve their ingestion of the -page 460 page 461 predominantly nicotine, but other substances in the 1 tobacco, tobacco smoke. 3 Q Isn't it true that research into compensation began in the late 1960s? 4 A I don't know when it precisely began, as in 5 6 when the first article was published. I know that there was not a substantial body of information that allowed 7 us to truly understand the extent of compensation at the 8 9 time that we did the 1981 Surgeon General's report. But there was a body of literature that existed at that 10 point in time. And so whatever its initial point was, 11 it was. It was prior to that time. 12 13 Q Compensation had significance for low delivery 14 cigarettes because if people compensated completely when 15 they switched to low delivery cigarettes, there wouldn't really be a difference that they would get, or benefit 16 17 that they would get out of switching cigarettes; 18 correct? 19 A Compensation is an issue for any change in 20 cigarettes. 21 Q Including that change? 22 Including the addition of filters, including 23 the manufacture of cigarettes, such that they produce a 24 low yield, including the use of ventilation to produce a page 461 page 462 1 lower yield in the cigarettes. 2 It also is a factor in design of cigarettes 3 relative to whether or not one would add nicotine to the 4 product. Q Isn't it true that the tobacco industry 6 sponsored the first publications in the scientific

7 literature on the subject of compensation? 8 A I don't know who sponsored the first 9 publication. I've already testified that I don't know 10 when the first publication was published or who do it. 11 I also don't know who sponsored it. 12 Q Are you aware of anything that has been known 13 by the tobacco industry concerning compensation that is 14 not also published in the scientific literature? 15 A I know that there is a substantial body of 16 internal tobacco industry documents that defined the 17 relationships between design of cigarettes and the yield of those cigarettes when they were smoked as they would 18 be smoked that was not available at that time to the 19 20 scientific community. Subsequently much of that information has become available both by release of 21 22 those documents and by replication of some of those experiments in the general scientific literature. 23 24 MR. BERNICK: Could you read my question, page 462 page 463 1 please? 2 (Record read.) THE WITNESS: Perhaps you could define the time 3 4 frame you would like me to address that? 5 BY MR. BERNICK: 6 Q Any time. 7 A I think I've addressed that any time. The issue was one of a time lag. That information was 8 available to the tobacco companies at a point in time at 9 10 which it was not available to the general medical 11 literature. Q That --12 13 A If you're asking me now whether there's 14 information that is not known now that the tobacco 15 companies have, I don't have access to the information 16 that is not known now that the tobacco companies have. 17 Therefore, I can't answer your question. 18 Q My question is much simpler. The tobacco 19 industry does a study internally. Same study is done 20 externally. Same conclusions reached externally. 21 That's what I'm focused on. I'm asking you whether the 22 tobacco industry has known anything about compensation as a result of its internal research which was not also 23 24 known at the same time to outside scientists as a result page 463 page 464 1 of their own research? A Yes. And I have answered that question. The 3 tobacco companies have known the effects of their design on the yield of those products when they were smoked as 4 they knew they would be smoked. They knew that at the 5 6 time at which they were designing those products, which 7 was well ahead of the time that those products were 8 either on the market or had been tested by independent 9 investigators and published in the literature. So that information was available to the tobacco companies at a 10 11 time at which it was not available to the general 12 scientific community. Q You're telling me that the tobacco companies 13 14 had compensation information that was specific to brands 15 that were not yet on the marketplace? 16 A I'm telling you that internal review of tobacco 17 industry documents by me includes review of documents

where they describe the design intent and design effects 18 19 of the changes that they were engineering into 20 cigarettes. Those cigarettes and those engineering 21 changes did indeed come to the marketplace. 22 Q Do you know that? 23 A I know that those changes in cigarettes did wind up in cigarettes. I also know they were testing 24 page 464 page 465 1 brands of cigarette that were already on the marketplace ahead of the time that similar testing was being 2 conducted and published in the scientific community. 3 Q There are people within the public health 4 community, including the Public Health Service, that 5 6 have endorsed general reduction, that is, the reduction 7 of smoke delivery, since the mid 1960s; correct? A You'd have to be more precise in your time 8 9 frame. 10 Q The Public Health Service in 1966 issued a 11 statement encouraging the tobacco industry to reduce the 12 deliveries of tar and nicotine in its cigarettes; true? A That is absolutely true, and the encouragement 13 was to reduce the delivery to people. 14 15 Q And isn't it true that since that time the 16 policy of encouraging general reduction has been 17 revisited from time to time? 18 A That's correct as well. Q And isn't it true that even after it became 19 20 known that people who switch from high delivery products 21 to low delivery products compensate at least to some extent, even after that became known the public health 2.2 23 authorities have still endorsed the general reduction of 24 smoke deliveries by the tobacco industry; correct? page 465 page 466 The public health community has consistently 1 endorsed the prospect of delivering less tar to the smoker. 3 4 Q Now, the concept, the driving idea behind 5 general reduction from the point of view of the public health community was to potentially reduce risk to the 6 7 smoker; correct? A Well, it was to reduce disease occurrence in 8 9 smokers, that's correct. 10 Q Okay. 11 A Not risk, but disease occurrence. 12 Q And over time people have done research on 13 whether lower delivery cigarettes, in fact, carry with 14 them a lower risk of disease to the smoker; true? 15 A Those studies have been conducted, that's 16 correct. Q And almost since the mid 1960s, the scientists 17 18 and public health authorities reviewing the data have 19 found evidence to support the idea that lower delivery 20 means lower risk, at least insofar as filter cigarettes 21 are concerned; correct? A They have found evidence to support the concept 22 23 that lower delivery to people would result in lower 24 risk. page 466 page 467 Q And that, in fact, the use of filter cigarettes 2 has reduced risk of disease to the consumer; true?

No. No. That is not true. There was evidence 3 4 early on that people who used those products had lower risk. We are in process of doing --5 6 Q I'm not -- I'm not talking about what we are in 7 the process of doing, Dr. Burns. 8 You're asking for my opinion on the topic. I want the question, I want the same question 9 10 read back. I'm going to ask you one more time, and this will be yet another subject we have to take up with the 11 12 judge. MR. GRUENLOH: You know, don't interrupt him in 13 the middle of his answers. It's rude, it's 14 unprofessional, and you've been doing it for two days. 15 I don't know how you can argue that he's not answering 16 17 your question when you don't allow him to finish. 18 MR. BERNICK: Could you please reread the 19 question? 20 (Record read.) 21 BY MR. BERNICK: 22 Q I'm asking you about information that was developed historically, Dr. Burns. 23 24 A And I'm trying to tell you what that page 467 page 468 1 information is, and you don't want to let me finish. Would you like me to describe the information? Would 3 you like me to --Q I'll make it easier. I'll go back through 4 individual things, and we'll just do the it the slow 5 6 way. Probably won't have to finish today. Probably 7 have to come back and do some more. A Well, that would be a matter of some 8 9 discussion. Q Well, I'm sorry, but I don't have -- you make 10 me do this. I've got no other choice. 11 12 A You won't let me answer your question. I'm 13 perfectly happy to answer your question. You're the one 14 that doesn't want to let me do it. 15 Q Are you familiar with FTC Monograph 7? 16 A Yes, I am. 17 Q That was issued by the National Institute of 18 Health? A Yes. 19 20 And that reflected a discussion by Dr. Samet of 21 the question of whether lower delivery products, in 22 fact, reduced the risk of disease to smokers? 23 A That's correct. 24 Q And do you remember that Dr. Samet reviewed in page 468 page 469 Monograph Number 7, which came out in 1996, the data 1 2 that he then had and concluded -- endorsed the conclusion that had previously been reached in the '81 3 4 report, that quote, "Today's filtered tip, lower tar and 5 nicotine cigarettes produce lower rates of lung cancer than to their higher tar and nicotine predecessors"? 6 7 That is what he wrote, that's correct. Α 8 Has Dr. Samet ever changed that conclusion? 9 Α I don't know whether Dr. Samet has changed that 10 conclusion. 11 Dr. Wald reported the study in 1995, again on 12 the question of whether lower delivery cigarettes 13 carried with them a lower risk of disease to the smoker;

14 15 He did, indeed, review that. He did, indeed, 16 publish that. And his examination was on people who 17 used those products. And his conclusion again was that lower 18 delivery cigarettes carried with them a lower risk of 19 certain diseases, particularly lung cancer; correct? 20 21 That was his conclusion, that's correct. 22 And Sir Richard Dahl, in particular, has spoken 23 to this issue over time; true? 24 A He has spoken on various occasions with various page 469 page 470 1 opinions. 2 Q Okay. And do you know that he spoke to the 3 same issue very recently; that is, in a deposition that was taken this year? 4 5 A I have not reviewed that deposition. I can't tell you with certainty what it contains. 6 7 Q Do you know what his views are today about whether lower delivery cigarettes reduce risk? 8 A My understanding of his views today are that 9 there is a dichotomy in the data available from his own 10 11 study of U.S. physicians and the American Cancer Society 12 studies showing an increase in disease risk or a stable 13 disease risk, and the studies that have looked 14 cross-sectionally at various populations or otherwise at various populations would show a reduction in risk. 15 That there is evidence that he believes suggests a 16 17 reduction consistent with the introduction of low tar 18 and nicotine cigarettes in England, and that he is at this point in time certain that the reduction is not 19 20 proportional to the reduction in tar, but believes that there might be a reduction in the risk particularly for 21 lung cancer. That's my understanding of his belief. 22 23 (Deposition Exhibit 7 marked.) 24 BY MR. BERNICK: page 470 page 471 1 I'm going to show you as Exhibit 7 page 181 of the deposition taken of Sir Richard Doll on March 16 of 2 this year. And I've highlighted on this the lines 4 to 3 15. I want to have you read those for a moment. 4 5 Α Yes. 6 0 The testimony that you see from Sir Richard 7 Doll on Exhibit 7, is that a -- is Dr. -- is Sir Richard being reasonable when he makes the statements that he 8 9 does regarding reduction of risk as you read them on 10 Exhibit 7? 11 I think in light of the information that we 12 have as we sit here today, I think that the statements 13 that Dr. Doll has made in his deposition are ones that 14 are not consistent with the data that we have today, and 15 I believe that he might reconsider that on the basis of 16 that information. 17 So you think that Dr. Doll when he testifies, 18 as he does, that there has been a reduction of risk without reasonable doubt, is being unreasonable? 19 20 Α That is not what I said. 21 Q That's what I asked you. Do you believe that Dr. Doll is -- that Sir Richard is being unreasonable 22 23 when he testifies, as he has in Exhibit 7, that there 24 has been a reduction in the risk of disease beyond a

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page 471
page 472
1 reasonable doubt?
            MR. GRUENLOH: Object to form. Objection;
 3
     asked and answered.
 4
             THE WITNESS: Okay. I believe that Dr. Doll is
    being reasonable in that he is relying on the reviews
 5
    that had been conducted. What I said was in light of
 6
    the evidence we have today, I think he might reconsider
 7
 8
    that opinion.
    BY MR. BERNICK:
 9
         Q When you say the evidence that you have today,
10
    is this published or unpublished evidence?
11
12
         A This is evidence that has been presented at the
13
    Institute of Medicine and has been discussed in
14
    deposition. It has not been published. It will be
    published in the near future.
15
             If we confine ourselves to data that has been
16
17 published, Dr. Burns, is the statement that Sir Richard
18
    makes as you see in Exhibit 7 a reasonable or
19
    unreasonable statement?
20
             MR. GRUENLOH: Same objections.
             THE WITNESS: If you confine yourself to
21
22
    archaic data, Dr. Doll's statement is consistent with
23
    the statements that were made by the Surgeon General
     reports, by the report you just described by the
page 472
page 473
    National Cancer Institute, and therefore, are reasonable
1
 2
    statements.
 3
   BY MR. BERNICK:
 4
     Q I didn't ask you about archaic data. I asked
 5
    you about published date.
 6
         A You're asking --
 7
            Dr. Burns, I'll ask you again.
         A -- me to operate off an incomplete set of
8
9
     observations, and then you're asking me to offer an
     opinion about whether that information is supported.
10
11
         Q No. A much simpler question. Just focus on
12 the question that I ask you. If we confine ourselves to
13 the data that has been published, that is, we look at
14
    the data that is published today, is the statement that
    appears in Exhibit 7 by Sir Richard regarding reduction
15
16
    of disease from lower tar cigarettes, is that statement
17
    reasonable or unreasonable based upon the published
18
    data?
19
             MR. GRUENLOH: Same objections.
20
             THE WITNESS: At the time at which Dr. Doll
21
    made that statement, it was a reasonable statement based
22
    on the published data. That is not to say that it
23
     reflects current scientific truth.
     BY MR. BERNICK:
24
page 473
page 474
1
            Is there -- are there any published research
     papers, that's gone through peer review, appeared in a
 2
     peer-reviewed journal, are there any published research
 3
 4
     papers today which say that reduction of delivery does
 5
    not carry with it a reduction of risk of disease?
 6
            My understanding is that if you reduce delivery
 7
   to people, there is compelling data that you reduce the
 8 risk of disease. The issue is not whether if you reduce
    the amount of tar ingested by people there is a disease
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reduction. The issue is whether when people switch 10 11 brands of cigarettes, they actually reduce the yield. There is a substantial body of data, some of 12 13 which shows that when you look at cigarette ingestion, that there is incomplete compensation. Others that show 14 15 that the nicotine yield across the population is very similar across brands with very different nicotine 16 17 yields. That is, indeed, the body of science that we're 18 examining at this moment. And that is the information 19 we're trying to develop a new understanding of. Q I'm going to have that question read back one 20 21 more time, Dr. Doll -- Dr. Burns. And I'm going to see if you can answer it. And if not, I have no more 2.2 23 questions this afternoon. We'll just take it up with 24 the judge. I didn't ask for your personal views on what page 474 page 475 the scientific truth is today based upon data that's not 1 published or whatever. 3 I want -- I asked a question about the state of published science that's available to all of us in 4 published form. I want to know, are there any articles 5 that appear in the published peer review literature 6 7 which say that lower delivery cigarettes do not, in fact, result in any reduction of risk of disease? 8 9 Yes. There are a series of articles that have been published that examine the rise in adenocarcinoma 10 of the lung and that suggest that the newer low tar and 11 nicotine cigarettes may have resulted in actual 12 13 increases rather than decreases of the yield. Some of 14 that work has been done by Michael Tune (phonetic). Some of that work has been done by others. 15 16 There has also been publication of work comparing the death rates from lung cancer from the 17 American Cancer Society study and from British 18 Physicians study, both of which have been characterized 19 20 as suggesting that the introduction of low tar and nicotine cigarettes has not been accompanied by a 21 reduction in the risk of disease in those studies. 22 23 So yes, there is a body of data that is 24 published that suggests exactly what you asked me to page 475 page 476 1 opine on, which is that the reduction in risk does not 2 3 Q Can you identify a single peer review publication which shows that reduced delivery cigarettes 4 5 do not, in fact, result in a reduction of the risk of 6 disease? 7 A I have identified several of those for you --8 I have --9 A -- including the comparisons of the American 10 Cancer Society studies, including the work that Michael 11 Tune and others have done examining the changes in lung 12 cancer risk, and including the comparisons of the first 13 and second phases of the British Physicians studies. 14 Can you give me a citation? Q I can't cite them from anywhere. 15 Q An author and title or a date? 16 17 A Michael Tune. Richard Peto. Recent -- last several years. I can't tell you the specific, whether 18 19 it's '97, '98 or '99. 20 Q Anything that wasn't available to Sir Richard

```
when he testified in March of this year?
21
22 A I don't know what was available to Sir Richard
23 when he testified.
24
            MR. BERNICK: Okay. I'm done for this
page 476
page 477
    afternoon. I reserve my right to continue the
1
    deposition when we have the court review the questions
    that have been put. But I pass the witness to somebody
 3
 4
    else. Thank you, Dr. Burns, for your time this
 5
    afternoon and yesterday.
             THE WITNESS: Perhaps we could take a break?
 6
 7 Is that acceptable to the powers that be?
8
             MR. BERNICK: Off the record.
9
             (Discussion off the record.)
10
             THE VIDEOGRAPHER: Let's go off the record at
11 3:01 p.m.
12
             (Recess.)
13
             THE VIDEOGRAPHER: This marks the beginning of
14 Videotape Number 4 of Volume 2 in the deposition of
15 Dr. David Burns. We are back on the record at 3:12 p.m.
16
                          EXAMINATION
17 BY MR. STEIN:
18 Q Good afternoon, Dr. Burns. Nice to see you
19 again.
20
            Good to see you.
21
            I know that you haven't forgotten, but just for
22 the record, my name is Adam Stein, and I represent
   B.A.T. Industries in this action. I have just a few
23
24
    questions for you, and I will attempt to be brief.
page 477
page 478
1
             Now, the last time we met, other than
    yesterday, was at your deposition in the Blue Cross/Blue
    Shield case on May 5, 2000. Do you recall that?
 3
            I do recall that.
 4
 5
            And at that deposition I asked you a series of
         0
    questions about B.A.T. Industries and whether you
 6
    intended to offer any opinions at the trial concerning
 7
 8 B.A.T. Industries. Do you recall that?
9
         A Yes, I do recall that.
10
         Q And your answer was that it depended on what
11 you were asked. And I gathered from that that at least
12
    as far as you were concerned, that you are not intending
13
   to offer any separate opinions as to B.A.T. Industries.
14 Am I right about that?
15
         A You are correct.
16
         Q And is that also the case here?
17
         A That is also correct here.
18
         Q Now, you also testified that you were not an
   expert on corporate governance issues and did not review
19
20
   the expert report of B.A.T. Industries' expert,
21 Professor Robert Stobaugh, which analyzed B.A.T.
22 Industries' corporate structure, and concluded that its
23
    relationship with BNW and its other subsidiaries was
24
    consistent with generally accepted corporate practice.
page 478
page 479
    Is that just a fair summary of something you and I
1
 2 discussed at that point in time?
 3
    A I believe it's a fair summary of something that
 4 I only understand glimmerly.
 5
         Q Fair enough.
```

```
6
            Dimly in the mist.
 7
         Q Okay. But it is something that we talked about
    briefly?
8
9
            It is something that we talked about briefly,
10
    yes.
11
         Q And does that testimony remain the case today?
   In other words, you haven't reviewed Dr. Stobaugh's
12
13
    report in this case?
14
         A I have not.
15
            And you have not undertaken since May to become
16 an expert in corporate governance?
17
         A No, I have not.
         Q Since your deposition in May --
18
19
            And I can assure you that between now and the
20
    time of this trial I will not undertake such an effort.
21
         Q Okay. Since your deposition in May, have you
22
   reviewed any documents that relate specifically to
    B.A.T. Industries as opposed to any other defendant?
23
         A Not that I can specifically recall, no.
page 479
page 480
1
         Q In response to a question I asked you in your
    Blue Cross/Blue Shield deposition about what role, if
 2
 3
    any, B.A.T. Industries could have had in research
 4
    undertaken prior to its creation in 1976, you responded
 5
    in part by stating that -- and this is where the quote
 6
    begins, "It would strike me as somewhat reprehensible if
 7
    the legal process allowed a company simply to say,
    'We're going to put all our assets in something, call it
 8
9
    something else, and pretend we don't have any
10
    responsibility.'"
11
             Do you recall making a statement like that?
12
         Q Now, you also stated that you didn't know if
13
     that's what happened. And do you recall that?
14
15
         A That is -- I recall that, and that is still
16
    true.
17
            Okay. Have you learned anything since last May
18 that causes you to believe that B.A.T. Industries'
19 creation in 1976 as a holding company for BNW and
20 British-American Tobacco Company, was intended to shield
21 assets or to otherwise escape liability in cases like
22
    this?
23
            I have not.
24
         Q And I take it, then, from that answer that you
page 480
page 481
1 have not seen any documents that would support an
    opinion to that effect?
2.
 3
         A I don't believe so, no. None that I can
 4
    recall.
 5
            I also asked you at your May deposition whether
 6
    it was your opinion that B.A.T. Industries should be
 7
    liable along with the other defendants in that case for
 8
    the conduct identified in the complaint which you
9
    testified about or which is referred to in your expert
10
    report. Do you remember that?
11
         Α
             Yes.
12
             Now, when I asked you that question the first
13
   time around, I didn't include the fact that B.A.T.
14 Industries did not come into existence as the parent of
15 BNW until 1976. And when I asked you if could point to
16
    any conduct by B.A.T. Industries that supported your
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belief that it was a participant in the conduct
17
18 complained of, you referred to biologic research
19 undertaken in the period between the 1950s and the mid
20 1970s. Do you recall that?
21
         A That's correct.
22
         {\tt Q}\,\, Apart from biologic research in the 1950s and
     the mid 1970s, is there any other conduct that you
23
24
     attribute specifically to B.A.T. Industries that in your
page 481
page 482
    mind links it up to the conspiracy that is alleged in
1
    this case?
        A I just need some clarity. We're talking about
 3
     the holding company, not the --
 4
 5
         Q That's correct.
 6
         Α
            -- the other?
7
         Q That's correct.
8
         A I don't have any information specific to
9 actions of the holding company independent of the
10 actions of the other companies. However, they are
    structured, and I am not in a position of understanding
11
12
    the corporate structure enough to -- or the law enough
    to understand how those responsibilities should be
13
14 appropriately apportioned.
15
            I take it, then, that it remains the case that
16 you can't point to any specific document that indicates
17 that B.A.T. Industries suppressed or caused to be
    suppressed any research by its subsidiaries in any area,
18
    including specifically smoking and health?
19
20
         Α
            That's correct.
21
         Q Have you seen any documents that indicate that
22 B.A.T. Industries suppressed or caused to be suppressed
23
    information concerning the synergistic relationship to
     cigarette smoke and asbestos?
24
page 482
page 483
            No, I've not.
1
         Α
            Have you seen any documents that you can
 2
 3 identify sitting here today that indicate to you that
 4
    B.A.T. Industries was involved in alleged attempts to
    block or otherwise interfere with any proposed ban of
 5
    smoking in the workplace by Johns Manville or any other
 6
 7
    entity?
 8
        Α
9
             MR. STEIN: Thank you, Dr. Burns. I have no
10 further questions.
11
             THE WITNESS: You're a gentleman and a scholar.
12
             MR. STEIN: We'll leave that for others to
13 decide.
14
             (Discussion off the record.)
             MR. SCHROEDER: Why don't we go off the record?
15
16
             THE VIDEOGRAPHER: We'll go off the record at
17
     3:18 p.m.
18
             (Recess.)
19
             THE VIDEOGRAPHER: Back on the record at
20
     3:19 p.m.
21
                     EXAMINATION (Continued)
22
    BY MR. SCHROEDER:
23
     Q Dr. Burns, you remember my name is Tom
24
     Schroeder, and I had given up a balance of my time for
page 483
page 484
1 Mr. Bernick to ask some questions before his plane. So
```

I would like to continue my examination, if I could? 2 That would be fine. 3 All right. Would you agree with me, Dr. Burns, 4 5 that within a job category for an asbestos-exposed individual, that different people with that same job 6 7 category can have very different asbestos exposures? That is true on an individual level, yes. 8 9 You testified yesterday that in addressing an 10 impairment on pulmonary function testing that you 11 required, and correct me if I'm wrong, that there be an 12 impairment greater than approximately 20 percent of pulmonary function. I assume as against expected 13 pulmonary function for the individual. Is that fair? 14 15 Actually, what I believe I testified to was 16 that there are statistical algorithms that we use to 17 define with great precision the abnormal values. And we use those to define whether someone is normal or 18 19 abnormal. On the whole, as a rough rule of thumb, a 20 20 percent reduction is approximately the level at which 21 someone is abnormal. 22 Okay. And what I wanted to do is follow up 23 with you that if one were to adopt a rule based on your on-the-whole rule, what level of deviation would be 24 page 484 page 485 1 acceptable from the 20 percent, in your view, that 2 would -- that would either allow for a normal pulmonary function, that is, something slightly more than 20 3 percent that still would be normal, within your view, or 4 5 if it goes the other way, something less than 20 percent 6 that would be abnormal, in your view? Do you follow my 7 question? 8 I don't follow your question. And let me try and figure it out. The algorithms define where that 9 threshold of abnormality is. If you're talking about 10 whether those algorithms would be slightly above or 11 slightly below 20 percent, I would go and look at the 12 13 values that we generate with a specific pulmonary 14 function study in our laboratory. 15 If you're asking me whether the 20 percent 16 value as a number has around it a set of values that are 17 normal, so you have to get to 75 percent below 80 percent, before you consider it abnormal, no, that's not 18 19 the way it works. A hundred percent is what you expect to derive. We know that there are normal deviances from 20 21 a hundred percent, normal variation from a hundred 22 percent, but by the time you get approximately 20 23 percent down, you are in a group where you no longer are 24 included in that group that would be considered normal. page 485 page 486 And that is the threshold for defining somebody as 1 having an abnormal or functional decrement. Abnormal 2 3 test or functional decrement. 4 If I were to adopt a rule that anything less 5 than 80 percent on forced vital capacity would be deemed abnormal, is it not true that as an arbitrary rule as 6 7 applied to individuals, that I may find persons on occasion that would be less than the 80 percent who, in 8 9 fact, would not have abnormal pulmonary function tests as you would compare it to your algorithm? 10 11 A That would depend on the pulmonary function 12 measure being used, the methodology being used, and the

construct in which you were doing that, what it is you 14 were trying to accomplish.

Q And if we were using your algorithm that you use in your clinical practice on a day-to-day basis, would it not be true, then, under those circumstances?

A It would depend on the specific measure. If you're looking at something like the forced vital capacity, I believe that 80 percent is outside the normal range. I'd have to go back and look. It would depend somewhat on the age of the individual. If you are using a measure such as FEF 25/75, then a 20 percent rule might not include -- might not exclude everyone who page 486 page 487

1 is normal.

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- Q Okay. Is it true as one gets older, their pulmonary function declines naturally?
- A The measures of pulmonary function decline naturally, yes. That is accounted for in the algorithms that I described for you earlier. Age is one of the terms that goes into those equations.
- Q Would you agree with me that the measurement of abnormality on pulmonary function testing can depend greatly on the group, the comparison group that you use for what's a normal population?
- A Well, it -- with different published studies, 13 one has slightly different algorithms in terms of the percentage normal and abnormal that would be expected. To the extent that one is shifting demographic groups, such as using values for adults, for children, or using values for whites, for blacks, one can lead to abnormal characterization.

To the extent that one is using measures for 20 things such as DLCO, then there are some substantial differences in the normal values that have been reported by different groups.

23 And, for example, on that DLCO, would you agree 24 that the differences could exceed five percent on either page 487 page 488

1

side of the 80 percent?

- A I'm not sure specifically what you're referring to. The expected normal values predicted by the equations are substantially different when -- depending on whether one uses the equations from Salt Lake City or from other locations.
- And that's really what I was trying to get at. Could you give me the range -- when you say substantially different, can you quantify that for me in percentages as a departure from normal?
- A I would have to go back and look at that literature to give you a percentage variation. But it is large enough to be clinically significant.
- Q All right. Can you tell me, sir, whether it could be more than five percent difference between Salt Lake City on the one hand, and the other studies you mentioned that might be at the other end of the spectrum?
- 19 A I can't give you a precise quantitative 20 estimate without going back and reviewing that data. would not be surprised if it were of that order 21 22 magnitude or somewhat larger. But I can't give you a 23 precise estimate.

```
24
            Do you use the Salt Lake City data as a
page 488
page 489
     comparison group in your practice?
       A No. I believe we use another set of
 3
     algorithms, but I don't think it is the Salt Lake City
     data.
 4
 5
              Would you agree with me that the Salt Lake City
 6
     data, which is, as I understand it, composed of largely
 7
     a Mormon population, tends to have a group of people
 8
     that's used for comparison that have a higher lung
     function than you might find in other comparison groups?
9
            I don't believe that the Mormon population
10
     specifically has a higher level of lung function. The
11
12
    Mormon population living in Utah, particularly around
13
     Salt Lake, lives at altitude. And it is the altitude
    that I believe is the principal concern with using the
14
15
    values for DLCO derived in that population for the rest
16
    of the country.
17
             If one were to use the values of the Salt Lake
    City population as a comparison group for DLCO, what
18
19
    would that tend to show as compared to, for example, the
    group you use? Would they tend to make your patients
20
21
    look like they are slightly more impaired? Or
22
     substantially more impaired? Or would they make them
23
     look like they are less impaired?
24
            It would yield a higher predicted value which
page 489
page 490
1
     for any given level would generate a higher percentage
     abnormality.
 2
     Q Had you considered using the Salt Lake City
 3
 4
     comparison group for your practice?
 5
       A I had not specifically considered that. That
     is a decision made by Dr. Clausen in our group who runs
 6
 7
     the pulmonary function laboratory. I know that he did,
 8
     indeed, consider those values and felt that they were
9
    not the appropriate ones to be used here in San Diego at
10
    sea level.
11
         Q Do you know anything about a comparison group
12
    used in the state -- comprised, rather, of individuals
    from the state of Michigan?
13
         A You would have to give me a little more
14
     information than that. It's been a long time.
15
          Q It's developed by Dr. Miller at Mount Sinai?
16
17
          A It's been a long time since I looked at that
18
     specific literature, and I don't have a recall of that
19
     specific article, no.
20
            Would it be fair to say that if you wanted to
21
     compare a group of asbestos-exposed individuals and
22
     determine what their impairment of lung function is,
23
     that in order to get an appropriate comparison, that you
24
     should try to compare them to a group of other
page 490
page 491
     occupationally-exposed individuals who are, though, not
1
     exposed to asbestos?
 2
 3
            I'm not sure what your comparison is intended
 4
    to demonstrate. If your comparison is intended to
 5
     demonstrate whether they have abnormal function, then
    the appropriate comparison group would be individuals
 6
 7
     who have no exposure of any type. No smoking, no
 8
     occupational exposure to dust or other things, and no
```

9 10 If you're interested in whether occupational 11 exposures to dusts and all of the other things in 12 occupational environments are different when asbestos is 13 in the mix, then one would compare an asbestos-exposed 14 population to an asbestos-nonexposed population. To do that, one would have to do something to control for the 15 16 profound effects of cigarette smoking on most measures 17 of lung function. 18 If you have a group that's exposed to asbestos 19 and they're occupationally exposed, and by that I mean that they are tradespeople, okay, they work in trades 20 that involve asbestos, but they also are around other 21 22 substances that tradespeople could be around, 23 construction sites, etc., if you wanted to determine the 24 amount of pulmonary function impairment they had that page 491 page 492 you would relate just to their asbestos exposure, and you want to control for the other background exposures, who would you compare them to to give you the best 3 4 reading you think you could get to, hopefully, isolate 5 the asbestos exposure? 6 My recommendation, I think, in that setting 7 would be to compare them to a normal population, to define the magnitude of their reduction, and then to 9 examine the relationships of the various exposures within that population. I think that that would be very 10 difficult in the face of the dominant effect of 11 12 cigarette smoking on various lung function parameters. 13 One would have to control for that first, and then look for residual effects. 14 15 Another way to do that would be to try to 16 examine the known effects of exposures to each of the individual likely exposures, where the prospect of 17 looking for patterns of illness, such as the relatively 18 19 pure restrictive pattern found with asbestos exposure. 20 But is impossible, as far as I know, to get a 21 truly matched control group of people who are exposed to 22 asbestos in various occupations, and compared to another 23 group with absolutely identical smoking behaviors and 24 other exposures absent asbestos. That's an unrealistic page 492 page 493 1 expectation for a control group. Q Would you agree that the contribution, if any, 2. of smoking to lung function impairment can best be 3 measured by FEV1 over FVC measurement? 5 The question you're asking is expressed 6 globally. And if you express it globally, no, that is 7 not the best measure. The best measures are in order of 8 age at which they first appear. You can see changes in 9 the small airways with closing volume. You can see 10 changes in the small airways that progress to more 11 permanent changes, that is, ones consistent with chronic 12 obstructive lung disease, first in the FEF 25/75. You then see those measures translate into a reduction in 13 14 the FEV1. 15 The question I think you were driving towards 16 is, in a combined exposure where you have both 17 restriction present due to asbestos and obstruction due

to the effects of cigarette smoking, in that setting,

then the measure that gives the best measure of

18

19

obstruction is the FEV1 over FVC, and the best measure 20 21 of restriction is the total lung capacity. 22 When one has a pulmonary function analysis 23 done, typically -- that is in, I suppose in an office 24 setting like yours, or in a laboratory, in a page 493 page 494 pulmonologist's office, typically in the battery of 1 2 tests that are run is FVC one of the standard tests 3 that's conducted? 4 Α Yes. 5 Is FEV1 over FVC a standard test? 0 Yes. 6 Α Is TLC a standard test? 7 8 Α TLC is part of a more extended test, ideally 9 done with a body plethysmograph. It is a relatively 10 standard test in our institution. It varies in other institutions across the country, and is nowhere near as 11 widely available nor as easy to determine as is the 12 13 simple spirometric measurements of forced vital capacity 14 and FEV1. 15 Q And is DLCO something that's typically done as 16 a standard test in your office? 17 A It may be done as a standard test, or it may 18 not, depending on the individual laboratory. I believe 19 our lab does it as part of their routine spirometry, but 20 I'm not a hundred percent certain. 21 And the FEV 25/75, would that also be one of 22 the standard tests conducted? 23 A That would be -- that's not a separate test. 24 The test is a forced expiration. And the FEV1 and other page 494 page 495 measurements are standard measurements made from that 1 test. And so yes, most laboratories would calculate that value. The FEF 25/75 and MEF 25/75 mean the same 3 4 thing. They're just different terminologies for the 5 same measure. 6 Q If, then, I were to have an exam done of me on 7 spirometry, and done in your office, then the standard tests would include the FEV1, FVC and the FEV 25/75? 8 9 Did I say that right? A Yes. It would include those, plus a series of 10 11 other calculations. 12 Q All right. 13 Now, I just, for the record want to be clear. You wouldn't have that done in my office. You would 14 15 have it done in the pulmonary function laboratory at the 16 hospital. That's how we do them in our practice 17 setting. My office would simply produce a pile of paper 18 that might fall on you, is all. 19 Q And then if I had those tests done, would you 20 then be prepared -- and if I were a smoker and exposed 21 to asbestos, would you then be prepared to tell me what 22 you thought the contribution of smoking was to my 23 impairment and the contribution of asbestos to my 24 impairment? page 495 page 496 A If I was seeing you if my office, I would do a 1 2 history, a physical. I would explore your occupational 3 history. I would review your medical records. I would review your chest X ray and a variety of other

laboratory data, as well as your pulmonary function studies. And then I would be in a position to tell you what my best judgment was about the relative contributions of various types of processes to your current clinical setting, and how those were reflected 9 in your pulmonary function. 10

- Q Could you tell me that based on the pulmonary function results alone? The impairment issue.
 - A I'm not sure what you're asking.
- Could you tell me if I were a patient of yours and I had my pulmonary function tests run at your laboratory, and then came in and saw you as a patient, could you tell me what proportion of my impairment you believe was caused by my cigarette smoking, and what proportion of my impairment would be caused by my asbestos exposure?
- A Number one, that wouldn't be what I would do in practice, and we've discussed that. Number two, that would depend on the nature of the abnormalities present on your pulmonary function. If your pulmonary function page 496 page 497
- was absolutely normal, I would obviously be able to tell 1 you that there was no evidence of pulmonary function 2. 3 abnormality.
 - Sure. Q

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- If you had a profound obstructive defect, then I could tell you that the principal consequence that you had suffered was likely due to cigarette smoking. If you had a reduction in a forced vital capacity with preservation of your expiratory flow rates, then I would tell you that your principal effect was one of asbestos exposure. If you had a combination of those, with very small lungs, and a marked degree of expiration, I would tell you that you had a substantive contribution from both.
- And could you then tell me based on the pulmonary function results how you would allocate that substantive contribution, percentage-wise, to asbestos 18 versus tobacco based on how you read my pulmonary function results?
- A You would allocate that based on the judgment about the extent of the disease that was present that was restrictive in comparison to the extent of the disease that was obstructive. There are, of course, individual cases where that allocation would be more page 497

page 498 1 difficult.

- Q Okay. By and large, is it fair to say that you could make that allocation in most people based on the pulmonary function results?
- A That would depend on what the results were. In the vast majority of individuals that you examine, there is not severe mixed disease. Okay? And those individuals with severe mixed disease, it can be quite challenging to allocate the disease to restriction and obstruction. In those instances where there is a predominant disease, it is much easier.
- 12 Q Okay. In the 1985 Surgeon General's report you 13 wrote -- and I say you, because you were the -- either 14 author or had the editorial control over it. You wrote 15 that, "It's clear that if cigarette smoking contributes

to the development of interstitial fibrosis in 16 17 asbestos-exposed workers, the contribution is a minor one in comparison with effect of asbestos dust 18 19 exposure." Do you remember that? 20 Yes. That's correct. 21 Do you agree with that? 22 I agree with that that the mechanistic basis 23 for the development of the interstitial fibrotic pattern 24 that we characterize as consistent with asbestosis is page 498 page 499 predominantly the result of exposure to asbestos. That 1 there are minor contributions to fibrosis produced by 2 cigarette smoking. I have modified that since that time 3 4 based on information that has become available that 5 there does appear to be evidence that people who smoke are likely to have a higher asbestos burden in their 6 7 lung, perhaps from interference with clearance 8 mechanisms. And, therefore, they might have greater 9 asbestos exposure-causing fibrosis. I believe we --10 I think we covered that last time. 11 -- covered that. Α And is it fair to say based on that that it was 12 13 your opinion that while there's still more work ongoing 14 in that area, there lacks scientific consensus on the 15 clearance mechanism as being, in fact, the mechanistic 16 factor for the burden? Is that fair? That is fair. And there is also some ongoing 17 discussion about whether the burden is actually 18 19 increased. I mean, my reading of that evidence at the 20 moment is that the preponderance of the evidence 21 suggests that it is increased. But there is ongoing 22 discussion of that as well. Q And, in fact, what -- if the burden is not, in 23 fact, increasing, what's the other apparent result? 24 page 499 page 500 1 I'm not sure what you're saying. Α 2 Q You said there's evidence that the burden may, 3 in fact, be increasing. That evidence is based on X ray readings in prevalent studies? 4 5 A No. Those are based on, actually, as I recall, lung digestion studies. And I believe there's also some 6 7 animal experimental data to suggest that for a given 8 controlled amount of asbestos inhalation, that there's 9 greater retention in animals exposed to cigarette smoke. That's one potential explanation for the unequivocally 10 11 supported observation that asbestos workers who smoke 12 have higher abnormalities on chest X rays than asbestos 13 workers who don't smoke. 14 The other potential explanations are that with 15 cigarette smoking there is an influx of inflammatory cells into the lungs. Those inflammatory cells may 16 17 facilitate or accelerate or accentuate the response to 18 asbestos in the lung that results in fibrosis. There are probably other explanations that have been put 19 20 forward as well. 21 And it remains also possible, though, does it 22 not, that, in fact, there is no increase associated with 23 smoking? Isn't that one of the possible explanations as 24 well? page 500 page 501

1 Increased what? 2 Q Increased level of fibrosis that's caused by 3 cigarette smoking. 4 A You've mixed two pieces there. Okay? I don't think that there is substantive debate that cigarette 5 smokers who are exposed to asbestos as a group have more 6 7 severe X ray abnormalities than cigarette -- than 8 nonsmokers who are exposed to asbestos in the same 9 occupations. I think that's a relatively well-accepted 10 11 The question is, why is that happening? There are several possibilities why that may be happening. It 12 may be happening because of combined disease processes, 13 inflammation and fibrosis crossing thresholds earlier. 14 15 It may be because there is a greater retention of 16 asbestos fibers in the lung, and therefore, a greater 17 exposure to asbestos. It could be because of damage due to smoking 18 19 interfering with the clearance of the lung. Or it could 20 be due to the inflammatory response produced by smoking in the lung facilitating the fibrotic response produced 21 by asbestos in the lung. And there may be other 22 23 explanations as well. 24 And one of the other explanations might include page 501 page 502 the fact that if more fibrosis is seen among smoking 1 asbestos workers, it could be not a causal relationship, 2. but related more to the fact that asbestos workers who 3 4 smoked tended to be the asbestos workers who also had 5 more asbestos exposure; is that a fair interpretation of a possible result? 6 7 A I think that was one of the issues that was of concern in the epidemiologic literature that examined 8 those questions. I think, it is my belief, that that 9 issue has largely been put to rest. That there is, 10 11 indeed, a real, i.e., not explainable by differences in 12 occupational exposure, difference between smokers and 13 nonsmokers. 14 Can you point me to what literature you would 15 rely on for that proposition? A There's a variety of literature that has 16 examined that. One of the pieces that I think 17 18 synthesizes that reasonably well is Dr. Nicholson's 19 report in this litigation. 20 Q Have you read Dr. Nicholson's report? 21 A I have. 22 Q You're aware of the fact, are you not, that the 23 studies he relies on principally are smoking-prevalent 24 studies that look at smoking versus nonsmoking among page 502 page 503 1 asbestos workers for potential parenchymal abnormality; 2 right? 3 I think your question is not phrased correctly. 4 I don't believe that they were smoking-prevalent studies. I believe that they were 5 6 studies of the prevalence of chest X ray abnormality in 7 populations. 8 Q That's what I meant. And you would agree that 9 that's what he principally relies upon? 10 A Most of those studies were cross-sectional 11 studies that define the prevalence at a point in time of

abnormality, yes, that's correct. 12

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Q Would you agree with me, Dr. Burns, that when you look at the more recent multivariable regression studies that look at the same question of whether smoking increases the level of parenchymal abnormality among asbestos workers, that the multivariate studies show that in some cases there is no smoking effect, and that in other cases, if there is a smoking effect, it cannot be distinguished statistically from background? Would you agree with that?

A It would not surprise me given the variability in the data that it is very difficult to model that data. I would have to go back and look at specific page 503 page 504

articles to respond appropriately to your question. Even in the cross-sectional studies not 100 percent of those studies showed a difference between smokers and

But I do believe that the preponderance of the evidence at this point in time, since you asked, is that smokers have a higher frequency of abnormal chest X rays by the ILO classification. That is true for smokers as a group compared to nonsmokers, absent asbestos in both groups. And I believe that that is the consensus view of the evidence for asbestos-exposed populations. The difference, I think, is in one of how big that difference is and how broadly applicable across all of the ILO classifications schema it is.

- Q Do you intend to offer an opinion in this case as to what that difference would be as applied to the Manville Trust claimants?
- A I have done no analysis of the Manville Trust claimants and do not expect to offer any information or testimony specific to the Manville Trust claimants other than those things that are present in the general medical literature.
- 23 When you reviewed Dr. Nicholson's report you 24 saw, did you not, that as to pleural plaques he reported page 504 page 505

his opinion that smoking actually causes an increase in 1 2 pleural plaques among asbestos-exposed individuals; 3 right?

- Α Yes, I did.
- And did you notice as well that his conclusion did not reach a statistically significant result as based on a 95 percent confidence interval? Do you remember that?
- My recollection is that he reviewed that, and when he included all pleural change, it was significant. But when he limited it to pleural plaques, he did not find a significance. But I would have to go back and look at my piece with more recency if you want me to opine on it.
- All right. And is it fair to say that to the extent he finds an increase -- strike that.

To the extent that Dr. Nicholson concludes that there is an increase of pleural plaques due to smoking, that that's his opinion, that to the extent he does say that in his report, that you would disagree with that?

A It is my view of that evidence, okay, that it does not support a causal relationship to smoking.

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Q Thank you. And as to Dr. Nicholson's analysis
23
24 of the apportionment of excess risk in lung cancer
page 505
page 506
    between asbestos and smoking, based on your testimony
    you gave, I think this morning, and probably some
    yesterday, is it fair to say that you essentially agree
 3
    with his analysis as he sets it forth in his report?
         A I don't disagree with his analysis. I think
 5
 6
    that that is a valid approach to this problem. My
 7
    preference is to do that with somewhat more specificity
    on the actual population. But I think that it is
8
    certainly a legitimate approach that he is taking.
9
         Q Okay. And, in fact, in your 1982 book, which
10
    was Exhibit, I believe, Number 4, on page 142 -- and I
11
12
    think there's a copy in front of you there, Dr. Burns.
13
         A Okay.
         Q Could you take a look at that?
14
15
         A The "Asbestos, Smoking and Disease"?
16
         Q Yes, Doctor. On page 142.
            Let's start with page 141, if we can.
17
18
             Okay.
19
            Do you see page 141 there's an introduction to
         0
20 the section on lung cancer? I believe that's what that
21 is.
22
        A No, it's actually an introduction to --
23
         Q The interaction section.
24
         A The whole interaction section, yes.
page 506
page 507
            That's fair. This sets forth the summary of
1
     some of the conclusions that are to follow in the
 2
    chapter; correct?
     A Well, it sort of lays out how we're going to
 4
 5
    approach it, yes.
         Q All right. And you say there in the second
 6
 7
    paragraph that --
8
         A Second paragraph, beginning with, "In general"?
9
         Q Hold on just a minute. I think that's where I
10 want to go.
11
         A Okay.
12
         Q Well, actually, in the first paragraph, the
13
    third sentence, do you see where it says, "It is clear
14
    that both agents," referring to asbestos and smoking,
15
    "produce a broad range of responses in exposed
16
    individuals"?
17
         Α
            Yes.
18
            And, "Therefore, it is not surprising that
19 these agents have a number of complex interactions in
20 the health of individuals with combined exposures." Do
21
    you agree with that today?
         A I agree with that today.
22
23
         Q Then in the next paragraph you say, "In
24 general, cigarette smoking and asbestos exposure might
page 507
page 508
     interact in a number of ways." And you say it might in
 1
 2
    the following ways; right?
            That's the word that was used, yes.
 3
 4
            All right, fine. And you say, "Both agents
    might produce the same disease. For example, lung
 5
    cancer. The combined exposure might result in a number
    of cases equal to the sum of the two agents acting
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separately, an additive effect." Do you see that? 8 9 A I see that. I'm unsure as to what you're 10 asking me to do other than validate the fact that those 11 words are present. Is that all you're asking me to do? 12 Q No. At that point, yes. Now I'm going to ask 13 you, do you agree with that today? A I agree --14 In some cases that that exposed -- the combined 15 16 result might be an additive effect? 17 A I think you're misunderstanding this paragraph, 18 or this set of issues. 19 Q Well --20 This set of issues is simply identifying Α 21 theoretically the various potential forms of interaction that might exist. It is not an effort to define the 22 23 nature of those interactions. It is simply laying out the various forms of interaction that might potentially 24 page 508 page 509 1 occur. The subsequent chapter actually deals with the data and whether those interactions do occur. 3 Q Would you agree with me that there can be circumstances on low asbestos exposure and low tobacco 4 5 exposure where you might have the two agents acting 6 separately and producing an additive effect? Is that a 7 possibility? Are you talking about for lung cancer? 8 Α 9 Yes. Okay. My understanding of that literature, and 10 11 my understanding of both the epidemiology and the 12 biology, is that, no, that is not true; that what happens is if you have very low dose exposures, you have 13 14 very low risks that are multiplied. When you multiply a risk, say, of 10 for smoking by a risk of point 1, okay, 15 for asbestos exposure, because there's a very low dose 16 17 of asbestos exposure, then one would have a tiny 18 adjustment in the number 10, and that that would not be 19 easily differentiable. 20 That multiplying 10 by point 1 would give you a 21 11. That might not be easily differentiated from 10.1, which would be the additive effect. And so in some 22 23 studies you might have the appearance of addition. But my understanding of the way this is viewed 24 page 509 page 510 scientifically is that that is a multiplicative 1 interaction throughout the entire range of the dose 2 response relationship. It's just as you get to very low doses, the difference between multiplying something and 4 5 adding it becomes very small in absolute terms. 6 Q Can you cite to me, Dr. Burns, what literature, 7 what studies you rely on that establish that at low dose 8 exposures the relationship is multiplicative and not 9 less than multiplicative or, indeed, perhaps additive? 10 The basis of that opinion is the general biologic literature on the effect of carcinogens on the 11 occurrence of lung cancer, or on the occurrence of 12 13 cancer. And that is a multistep process occurring 14 sequentially with large numbers of steps over a period 15 of time. That what we understand about that process is 16 17 that there is no threshold below which an effect 18 disappears, but that the effect is proportional to the

dose and potency of the carcinogen that it appears over 19 20 time. Okay? 21 That is then combined with the evidence that 22 exists on asbestos exposure in various different settings, okay, where the magnitude of the asbestos 23 24 exposure has been shown to influence the magnitude of page 510 page 511 the risk. And so there is a clear dose response 1 2 relationship that almost everyone feels exists for asbestos exposure and the occurrence of lung cancer. 3 There is also a very clear dose response 4 relationship with no threshold for cigarette smoke 5 exposure and the occurrence of lung cancer. In the 6 7 studies that have examined those issues, okay, of 8 synergy where you have combined data, it appears that the multiplicative interaction which was demonstrated at 9 10 high doses of both in the Selikoff data appear to 11 persist as you go down to lower doses of asbestos 12 exposure and lower relative risk of lung cancer. 13 And that, therefore, when you put all of that together, you would -- you are left with a statement or 14 15 a conclusion that this -- the evidence exists that the 16 dose response relationship exists throughout the entire 17 range of doses; that the multiplicative interaction 18 appears to exists for all ranges of doses where it can 19 reasonably be expected to be demonstrable. And therefore, it is reasonable to expect that it would 20 persist below those levels at which it is possible to 21 22 measure because the magnitude of the effect is so small 23 that one cannot see it. MR. SCHROEDER: Could you mark that for me? 24 page 511 page 512 Q Can you cite to me a study for that proposition 1 that involved -- let me preface this. There are, I believe, approximately 12 -- approximately 12 studies that provide data that are sufficient from which one can 4 5 draw quantitative conclusions as to whether there's 6 interaction that deal with the issue of lung cancer in 7 asbestos and smoking. 8 Can you cite to me a study that supports the proposition that at low levels of asbestos in smoking 9 10 exposure there is, in fact, a multiplicative effect? MR. GRUENLOH: Objection; form, foundation. 11 12 THE WITNESS: You're asking for a study on 13 something that cannot be demonstrated. I believe that 14 there have been reviews of the relationships across different studies that have suggested that for the 15 16 ranges where an effect is demonstrable and measurable, 17 that there appears to be a multiplicative action. 18 What we understand about the normal course of 19 examining lung cancer, or any cancer, is that you would 20 back-extrapolate from those dose response curves. That 21 is a relatively standard practice that is used routinely 22 in examining occupational carcinogens and other 23 exposures. 24 And so I can't point you to a specific study page 512 page 513 that looks at something that is not measurable and not 1 definable, because that study is not possible to do. 3 What I can point you to is examinations of that

body of literature that suggest that the multiplicative 4 interaction is operative over the full range of dose 5 response relationships that have been established for 6 7 asbestos where that has been examined in any way that 8 you could measure it. 9 And then I'm simply making the assumption that is widely used in looking at low dose exposures, which 10 11 is to extrapolate downward from higher dose exposures 12 where you have good data because of larger effects to 13 impute what is likely to happen with lower dose 14 exposures. 15 BY MR. SCHROEDER: Q What authority do you rely on that you would 16 17 cite me to for the latter proposition? And that is, 18 people who, I think you said, have drawn that conclusion 19 based on other literature that you can look at low dose 20 exposures and still reach the same result? 21 A There is a substantial body of literature 22 around risk assessment measures for environmental 23 factors for exposures both for respiratory disease and also exposures particularly for occupational carcinogens 24 page 513 page 514 1 where the data routinely is taken from higher dose exposures where there is human data and extrapolated 2 3 downward to establish thresholds for acceptable occupational levels for those exposures. 4 5 That is routinely done by the Environmental Protection Agency, by various other groups that set 6 7 threshold limits. And I believe that there are review 8 and -- I don't know whether they would be guideline 9 documents or other documents, that the FDA and other 10 groups have prepared on risk assessment that support 11 that approach. Can you point me to a document that deals with 12 Q 13 that issue in the context of asbestos and smoking? And if so, I would like to know what name -- either the name 14 of the document or the author if you could, please. 15 A I believe that there is an examination of that 16 17 issue -- I think it has been examined by several 18 individuals. There have been several reports that I'm 19 familiar with. There is at least one published, I believe by Julian Peto, but I could be wrong, some 15 or 20 21 20 years ago now that looks at the data for lung cancer 22 and defining a dose response relationship with fiber 23 years of exposure and extrapolating that down to a 24 relative risk of one. That is, no background risk. page 514 page 515 I believe that others have done similar type of 1 extrapolations from the data. I believe that either 2 Newhouse or Berry have done that type of calculation. I 3 believe as well that McDonald has done that type of 4 5 calculation based on the mining data. б There has also been that type of assumption 7 that provided the core substrate for examination of very low dose asbestos exposure in the general environment, 8 9 and that was a report that was published some 15 years ago or more that defined the -- maybe less than 15 years 10 11 ago. I think it was shortly after the 1985 Surgeon 12 General's report. That defined the impact of or 13 expected impact of nonoccupational exposure to asbestos; 14 that is, schools and buildings, etc. And so there's a

wealth of documents out there that have done that in 15 16 relation with asbestos. 17 Q In connection with smoking? I think I limited 18 my question. 19 Yes, in connection with smoking. 20 The data from the British studies, Newhouse and Barry, control for smoking. And I believe that some of 21 22 the McDonald data control for smoking, although I'm not 23 certain on that one. I do know that the estimates are 24 generated differentially for smokers and nonsmokers. page 515 page 516 And the report on ambient asbestos exposure, that does 1 2 that downward extrapolation. 3 Q Is the Barry study you were referring to the 4 same one we talked about either earlier today or yesterday afternoon? That is, Barry 1972? 5 6 A No. It is that subsequent body of work that 7 has been published. 8 Perhaps we could take a short biologic break 9 here. 10 MR. SCHROEDER: Okay. 11 THE VIDEOGRAPHER: Off the record at 4:04 p.m. 12 (Recess.) 13 THE VIDEOGRAPHER: We are back on the record at 14 4:12 p.m. 15 BY MR. SCHROEDER: Dr. Burns, let's go back to page 141, if we 16 17 can, of your book. 18 Α Okay. 19 And you say there, do you not, in the paragraph 20 numbered number 1, that, "Both agents," that is, smoking 21 and asbestos, "might --" "combined exposure from both, 22 rather, might result in a number of cases equal to the sum of the two agents acting separately an additive 23 effect"; isn't that correct? 24 page 516 page 517 That is the correct reading of those words. As 1 2 we've discussed previously, that is the initial step in laying out the potential or hypothetical ways, in 3 contrast to actual ways, that smoking and asbestos might 4 5 interact. 6 Q But you don't say here, though, do you, Doctor, 7 that, in fact, this is only a hypothetical; that is not, 8 in fact, what could be occurring? 9 I believe that a reasonable reading of that 10 introductory paragraph in the first sentence would lead 11 the reader to believe that what we were doing was laying out the potential ways that asbestos and smoking might 12 13 interact as a basis for them reviewing the data to 14 describe how it actually interacts. 15 Okay. 16 A That was certainly my intent in writing it. 17 And if I did not effectively communicate that, then that is a limitation in my communication skills. 18 Q On page 142 in the first paragraph under "Lung 19 20 cancer," in the second sentence you say, do you not, "In 21 all of the groups studied," and that is studied for 22 interaction, "those workers with a combined asbestos and 23 smoking exposure had more lung cancer deaths than would 24 have been expected from the sum of the independent page 517

page 518 effects of cigarette smoking and asbestos exposure, 1 indicating that there is a synergistic effect of the combined exposures on lung cancer death rates"; right? 4 A That's correct. 5 And do you agree with that today? Q I agree with that. 6 7 The next sentence says, does it not, that, "The 8 magnitude of the synergism varies somewhat in the 9 different populations studied as would be expected from 10 the differing exposures to asbestos and different smoking behaviors"; is that correct? 11 12 A That's correct. 13 And do you agree with that statement today? Q 14 15 And so what you are saying is that depending on 0 16 the exposures to asbestos and smoking, the level of 17 synergism, as you define it, that is, a departure from 18 additive model, depends on what those independent 19 exposures are. Is that a fair statement? A I think that's a potentially mischaracterized 20 statement of what I've said. What I'm saying there is 21 that there are different doses of exposure to asbestos 22 23 in different studies. There are different doses of 24 exposure to smoke in different studies. And therefore, page 518 page 519 the combined risk comes out differently. 1 Q Well, the magnitude of the synergism, as you 2 3 state here, refers to the level of synergism, that is, 4 whether it is additive or all the way to the level of multiplicative, does it not? 5 6 No. Magnitude is, in general, a quantitative 7 effort. The synergism is the combined effect above that to be expected from the independent exposures. That is 8 a function of magnitude of the independent exposures. 9 10 If you have a higher level of asbestos exposure, you 11 will have a higher magnitude of the synergistic effect. 12 If you a higher level of smoking, you will have a higher 13 magnitude of the synergistic effect. 14 If your relative risk, for example, from 15 asbestos exposure is 2, and your relative risk from smoking is 20, your multiplicative interaction would 16 17 be -- I'm sorry, relative risk from smoking is 10, your 18 relative -- your multiplicative effect would be one of 19 20. 20 If your relative risk from asbestos is 5, and 21 your relative risk from smoking is 10, your 22 multiplicative interaction would be 50. The magnitude 23 of that synergistic effect would be dramatically 24 increased. page 519 page 520 1 You remember the 1980 study that Dr. Selikoff did of the Amosite factory workers? Which one? The one in short-dose exposure? Is 3 4 that the one you're referring to? 5 The one of approximately 500 factory workers 6 where he found an approximately 80 times risk based on a 7 comparison to totally unexposed individuals. 8 A I'm generally aware of that. It's been a while 9 since I've looked at that particular study. 10 Q You recall, do you not, that in that study

Dr. Selikoff concluded that the relative risk for 11 12 asbestos exposure alone for lung cancer was 13 approximately 25? 14 A I know that that number has been in the literature. I know that it is based on small numbers. 15 16 I know that when we examined that study for the Surgeon General's report, we didn't feel that the data were 17 18 sufficiently precise in their estimation to include it. 19 But -- include that as an estimate, 25. 20 How many deaths among nonsmoking asbestos 21 workers do you recall were reported in that study? A As I said, it has been a while since I reviewed 22 23 that study. If we need to talk about it in that level 24 of detail, I would need to look at the actual paper. page 520 page 521 1 Q How many deaths among nonsmoking asbestos 2 workers were reported in the 1979 Hammond study? 3 A Approximately 450. 4 Q I'm sorry, how many deaths among nonsmoking 5 asbestos workers were reported for lung cancer in 6 the 1979 Hammond study? 7 A Depending on the criteria you use, either four 8 or five. 9 Q Okay. And when using death certificate, it was 10 four, was it not? 11 A I believe so. Do you recall whether the number of deaths in 12 13 Hammond -- in Dr. Selikoff's 1980 study for nonsmoking 14 asbestos workers was actually larger than the number of 15 deaths in that '79 study? A I'm sorry? 16 Q Do you recall whether the number of deaths for 17 18 lung cancer among nonsmoking asbestos workers that were in Dr. Selikoff's 1980 study was actually larger than 19 the number of deaths in the '79 study for the same 20 21 group? 22 As I said, it has been a while since I have 23 reviewed the Selikoff 1980 study. It would take me some 24 time to review that. In order to talk about the details page 521 page 522 of the number of deaths, etc., it would require that I 1 go back and look at that study again. 3 Q Would you agree with me, Dr. Burns, that the 4 precision of statistical estimates increases when you 5 have more deaths to study in epidemiological studies? 6 A Well, all other factors being equal, a 7 statement that is never true in epidemiologic studies, the number of deaths increases the precision or the 8 reliability of the estimate. That is dependent, then, 9 on other factors, such as the quality of the data that 10 11 you're using and the population you're examining. 12 On page 142 of your book in the next to last 13 paragraph you say, last sentence, "However, the 14 numerical values of the multipliers may vary for both 15 asbestos and smoking with the time interval since the 16 beginning of exposure and on the intensity of the exposure." Do you agree with that statement today? 17 18 I do. Α 19 If one were to estimate the relative 20 contributions of asbestos in smoking for lung cancers 21 reported in a population of individuals, you would need,

then, to look, according to your statement here, to the 22 time interval since beginning exposure for each person, 2.3 the intensity of their exposure; is that correct? 24 page 522 page 523 1 Α No. 2 Why not? 3 If one is interested in making an estimation of Α 4 occurrence of disease or proration of disease or other 5 characteristics in the population, one can use the 6 information that is available. The precision or ability to define with small increments differences is enhanced 7 by having more observations and by having more accurate 8 information on the dose intensity and duration of the 9 10 exposures in question. 11 If one does not have that, one drops back and 12 uses larger categories of data, as is commonly done in 13 occupational studies, such as occupation, or 14 occupational category, or industry group, or smoker, 15 nonsmoker, without categorizing the dose and duration of 16 smoking status. So any one of those approaches can be used to 17 answer those questions. The more data you have, the 18 19 more precise your estimates can be. But all of those 20 approaches can and have been used. 21 Q Do you know anything about the manner in which 22 the data work were collected, if at all for the Manville 23 Trust claimants on their actual exposures to asbestos? A I'm not sure what you're asking. I'm generally 24 page 523 page 524 aware that that information was collected as part of the 1 litigation. I'm generally aware that it was extracted from a combination of sources that vary across time, 3 including such sources as medical records, deposition testimony, affidavits or other filings by attorneys, and 5 presentation of information by attorneys. So there's a 7 variety of sources. I'm not specifically conversant with that data set or the methods by which that data 8 9 have been retained or tested in any way. 10 Q You don't know what percentage of the claims 11 files contained information about exposures apart from that reported by the claimant and/or his or her attorney 12 13 on the claim form, do you? 14 A As I've now said, I think four or five times, I 15 have not conducted any analysis or any examination on the individual claimants for the Manville Trust. 16 17 Q Okay. 18 A And that includes examining where the sources 19 of information came from. 20 Q Okay. Would you agree with me, Dr. Burns, that 21 the manner in which one collects information for an 22 epidemiological study can affect substantially the 23 validity of any of the results that you want to draw 24 from the study? That is, that you can have bias in the page 524 page 525 collection and reporting process. 1 A The more accurate the data is, and the more 2 3 free from bias the data is, the more valid and more 4 likely it will be to demonstrate a result. It is 5 uncommon for inaccuracies in data to generate a result that is not one that is true. In general, inaccuracies

7 in data interfere with the ability to demonstrate a result rather than demonstrating a spurious result. 8 As to bias, bias may influence the results in a 9 10 random way, or may influence the results in a systematic way. To the extent that it influences results in a 11 systematic way, it has the potential to distort the 12 effect that you're looking at, depending on the power of 13 14 the bias and power of the underlying effect that you're 15 looking for. 16 Would you agree with me, Dr. Burns, then, in 17 the context of persons making claims for compensation and reporting on a self-reporting basis the level of 18 asbestos exposure they may have had, however described, 19 20 whether by job description or by industry, etc., that 21 there is inherent in that process the likelihood of 22 23 I think that that's an overly broad 24 categorization. Okay? Certainly it is less likely that page 525 page 526 people are going to be biased in their descriptions of 1 where they worked, as that information may be readily accessible through a variety of sources. If you're 3 4 asking people to categorize their individual exposures, 5 some people may be biased in litigation, other people 6 will not. It is an issue that would need to be 7 considered. It is not necessarily one that would interfere with the calculation of effects. It's 8 9 potential, but not necessarily real. 10 Q Are you aware of any instance in which, in the 11 history of your involvement with Public Health Service 12 and the various public health groups, that anyone in 13 those instances has prepared for public health purposes epidemiological studies based on information filed by 14 claimants for compensation? And if so, please tell me 15 16 what they are. 17 I can't cite from memory that kind of 18 literature. I would be surprised if some of the data 19 sets that have been collected for purposes of litigation 20 have not resulted in some academic publications. But I 21 can't cite them specifically for you. Okay. 2.2 23 MR. MOLSTER: I move to strike everything after 24 the first sentence. page 526 page 527 THE WITNESS: Including the fact that I can't 1 cite them for you? 3 BY MR. SCHROEDER: 4 Q Let's move to page 145 of your book that you 5 did for Commercial Union. 6 A It's a bad sign that we're not getting ground 7 faster on this report. Go ahead. 8 Q You say in the first full paragraph there, 9 Dr. Burns, that, "An understanding of these dose response interactions, and of the changes over the years 10 11 in the exposure dose for cigarettes and asbestos, is 12 particularly important for projecting the public health 13 impact of this interaction on this population." 14 A That's correct. 15 Q Do you agree with that statement today? 16 A That's correct. 17 Q Would you agree with me that the individuals

who were exposed to asbestos in the Selikoff studies had 18 19 a heavier exposure to asbestos than individuals who were 20 asbestos insulators in the time period following the 21 period of study in the Selikoff studies? A I'm sort of at a loss as to what your question 22 23 24 The people -- let me rephrase it, then. page 527 page 528 1 The people in the Selikoff study were people Α 2 who were employed who had had 20 years or more since onset of exposure in that particular union. Okay? 3 That's a defined group. 4 Q Let me withdraw -- I'm going to withdraw the 5 6 question and rephrase it so we can get back on track. 7 A I need some definition as to the group you want 8 me to compare them to. 9 Q Would you agree that the people in the Selikoff 10 studies are more heavily exposed to asbestos than 11 persons who would have been exposed to asbestos in similar occupations in periods after the Selikoff study 12 13 was conducted? A Overall, as a large generalization, that is 14 15 probably correct. On the other hand, there are 16 obviously individuals and locations where the exposure 17 may have been very heavy. But on average, the people who form the cohort 18 of the Selikoff studies were, by and large, much more 19 heavily exposed than we tend to find in people who would 20 21 have been studied in periods after the people who were 22 studied in the Selikoff group; correct? A That's a different question than you had asked 23 24 previously. You had asked previously about insulators page 528 page 529 in other locations besides the Selikoff study. I think 1 that it is fair to say that the Selikoff population was 3 very heavily exposed. In general, okay, with obvious likely individual and group exceptions, they were more 4 5 heavily exposed than the insulators in other occupations all across the United States. 6 7 It is also true that the extent of asbestos exposure has diminished over time as standards for 8 9 environmental asbestos limitations have both been 10 reduced and been more aggressively and widely 11 instituted. So there over time has been a decline in 12 the magnitude or intensity of asbestos exposure at any 13 given work year. 14 Q When you say in this sentence we just referred 15 to that, "One needs to take into account the changes 16 over the years and the exposure dose for cigarettes," 17 what specifically are you referring to? 18 A There has been a decline in both initiation of 19 cigarette smoking, and also in the prevalence of 20 cigarette smoking over time. That change has occurred 21 nonuniformly across the population, both in terms of the 22 occupational exposures or occupational groups in terms 23 of the smoking behavior, and also in terms of age and gender differences across the population, as well as 24 page 529 page 530 1 racial differences across the population. And so one of the issues, if -- that if one has

the data, one should consider in examining future public 3 health effects is the impact that changes in smoking 4 behavior going forward in time are likely to have, or 5 changes in recent smoking behavior are likely to have on future occurrence of disease. 7 8 Q Wouldn't that come into account anyway in 9 applying under the way you look at it the level of 10 asbestos exposure in any population with the level of 11 smoking exposure, given the fact that you say it's 12 multiplicative? In other words, why do you need to take this into account when, in fact, when you look at any 13 14 given population you would automatically take that into account because you would look at whatever the smoking 15 16 prevalence was? 17 A If you are looking at the smoking prevalence, 18 then you are taking that into account. 19 Q Okay. 20 A You can take it into account with a variety of 21 different levels of precision, however. 22 Q You say in the last sentence that starts that page, "The asbestos multiplier," and you put it in 23 24 quotes, "either for groups of current workers who have page 530 page 531 1 been exposed only to these lower levels or for groups of older workers who have had low exposure levels in the past, should be lower than the multiplier derived for 3 older workers with high exposures." Do you see that? 4 5 A Yes. Q Do you follow? The multiplier you're talking 6 7 about is the -- the level of interaction between asbestos and smoking, is it not? 8 9 A No. It is the asbestos multiplier. In a multiplicative interaction there are two multipliers. 10 One is asbestos and the other is smoking in the context 11 12 of multiplicative interaction between smoking and asbestos exposure. This chapter -- or this paragraph 13 refers to the multiplier for asbestos. In the Selikoff 14 15 data, it would be -- the multiplier for asbestos is 5. 16 Q You say on page 146 in the bottom paragraph 17 that, "No one risk multiplier describes all smoking 18 habits or all asbestos exposures." Do you agree with that statement today? 19 20 A Yes. Q All right. On page 148, then, you talk about 21 22 cessation of both -- the effect of cessation on smoking 23 and the effect of cessation on asbestos exposure. You say that, "The relative risk due to asbestos exposure page 531 page 532 should stop increasing upon cessation." Is that a fair 1 2 statement today? 3 A I believe that that's a fair statement today, 4 5 Then you further say, though, "There's no evidence that this risk decreases with the time since 6 the last exposure." Is that a fair statement today? 7 8 A I believe that's a fair statement today. 9 Q However, the risk related to smoking, in fact, 10 decreases, I think you've testified many times before, upon cessation of smoking; correct? 11 12 A Relative to the risk of the continuing smoker. 13 MR. SCHROEDER: Okay. Let's mark this one.

```
(Deposition Exhibit 8 marked.)
14
15 BY MR. SCHROEDER:
16
     Q Dr. Burns, I'm now going to hand you what's now
17
    been marked as Exhibit Number 8.
18
19
            Do you recognize that as an exhibit that you
20
    used in your testimony in the Cimino litigation in
21
22
         A I believe it is, yes.
23
         Q And you testified in the Cimino litigation on
24
     behalf of whom?
page 532
page 533
             I believe it was on behalf of Pittsburgh
1
 2
     Corning.
 3
         Q And this chart that's shown as Exhibit Number 8
    is meant to show the relative risks of developing lung
 4
     cancer for occupations -- certain occupations of
 5
     asbestos exposure as related to cigarette smoking, both
 6
 7
    divided into current smokers and former smokers. Is
     that a fair statement?
 8
9
         A It is. It actually reflects individual studies
10
     in those occupations, yes.
11
         Q Does this chart reflect a fair representation
12 of those studies that address the various asbestos
13 exposures and smoking exposures as depicted on
14 Exhibit 8?
15
         A I think it's a reasonable description of the
    smoking exposures. It's not a complete description of
16
17
    the asbestos exposures. It is a relatively complete
18
    description of the high level asbestos exposures with
19
    high relative risks. It leaves out many of the studies
20
    that have been done in other occupations where the risks
21 are much lower, for example, chemical workers, or
     shipyard workers, railroads, those kinds of things.
22
     There is one study of shipyards.
23
24
         Q For purposes of the asbestos exposures as
page 533
page 534
1
    depicted on your Exhibit 8, these are fair
    representations of the studies in those asbestos groups,
 2
 3
    are they not?
         A They are representations of individual studies.
 4
 5
            I understand.
 6
            If one looks at all of the studies that have
7
    been done, okay, I think one will see that the risks are
     substantially lower on average when one looks at all of
8
9
    the studies. This was intended to show those studies
10
    with very high risks.
11
         Q And the high risks would be based on persons
12
     who had heavier asbestos exposure; correct?
         A In general that's correct.
13
14
         Q And in the Cimino case, the claimants in Cimino
15
    tended to be more heavily exposed, did they not?
16
         A I don't have evidence to describe their average
17
     exposure. My expectation from having seen a sample of
18
     those individuals was that they would be heavily
19
     exposed, yes.
20
             (Deposition Exhibit 9 marked.)
21
    BY MR. SCHROEDER:
         Q If you take a look at Exhibit Number 9, can you
22
23
     confirm for us that that's another exhibit you used in
24
     your Cimino testimony that shows the years of asbestos
```

```
page 534
page 535
1
     exposure based on duration for persons in the Cimino
            It was not part of my testimony. I don't
 3
    believe that it was allowed to be introduced in the
 4
     court. But it was certainly something we prepared from
 5
     some of the data provided on that population.
 6
 7
            Does Exhibit Number 9 accurately reflect as
 8
     prepared by you the duration of asbestos exposure for
 9
     the claimants you were dealing with in the Cimino case?
            It reflects the graphing of the data that we
10
     were provided on duration of exposure for that group.
11
         Q And you prepared Exhibit 9, or had it prepared
12
13
     at your direction; correct?
14
         A I prepared the graph. I did not collect the
15
    data.
            So the data was represented to you by the
16
17
    claimants or somebody on behalf of the claimants, and
18
    you then prepared a graph of it. Would that be fair?
         A My understanding is that the data was collected
19
20
    as part of an examination by questionnaire of the
    claimants conducted by the defense in the case. But I'm
21
22
    not a hundred percent certain of that.
23
            Okay. Looking at Exhibit 9, then, is it fair
24
     to say that Exhibit 9 shows that most -- the bulk, if
page 535
page 536
 1
     you will, of the claimants that you were dealing with in
 2
     the Cimino case had 20 or more years of asbestos
     exposure. Is that a fair statement?
 3
         A Yes, that's a fair statement.
 4
 5
            And that, in fact, many of them had between 30
 6
    and 40 years of asbestos exposure; is that a fair
 7
    statement?
             That's a fair statement.
 8
9
             Then if you go back to Exhibit 8, is it fair to
10
     say that the studies that you selected for inclusion in
11
    Exhibit 8 reflected the type of exposures that you would
12
    have found in Exhibit 9, so that it applied to your
13
    testimony in the Cimino case?
14
            I think that that's a complex question. Okay?
15
    Obviously there were very few people in that case that
16
    had mining exposure. There were a few, I believe, that
17
    had some friction exposure. Very few that had
18
    manufacturing exposure. A substantial number that had
19
    exposure to asbestos cement, but not in the same setting
20
    that the asbestos cement studies were conducted, in that
21
    they weren't in the manufacturing plants, per se.
22
              There were a number of people who were, indeed,
23
     insulators, spraying insulation. There were a fair
24
     number of people who had exposures in shipyards and in
page 536
page 537
 1
     work conditions that might be comparable to shipyards.
     That is, general maintenance and repair of facilities
 2
 3
     where asbestos was in the air in substantial amounts.
 4
             So in general, the duration of exposure would
 5
    have been probably roughly similar to some of these
 6
     studies. The intensity of the exposure could have been
 7
     somewhat less, might have been somewhat less. We didn't
    have data to accurately characterize it in that
     population.
```

10 As I said, my examination of a small group of 11 those individuals led me to believe that there was, indeed, a substantial prevalence of asbestos-related 12 13 disease in that population, suggesting that they had a substantive exposure over time. That exposure over 40 14 15 years certainly could produce a substantial frequency of disease, which was manifest in the examinations that I 16 17 conducted. 18 On Exhibit Number 8, is it fair to say based on 19 your earlier testimony that the levels of asbestos -- of 20 relative risk shown on the asbestos exposures based on what you said before, remained at that level once 21 they -- once the individuals were no longer exposed to 2.2 23 asbestos? 24 A I'm not sure what you're asking me. page 537 page 538 The level of relative risk individuals may have 1 had if they fell within the applicable comparison 3 cohorts that you've listed here on Exhibit 8, that is, the Cimino claimants, if they had a -- if they were in 4 5 manufacturing, for example, and you somehow testified that they fit into one of these cohorts, or at least 6 7 they had comparable exposures, in your opinion they fit, 8 that level of asbestos exposure would remain constant, 9 then, even after they -- the relative risk for lung 10 cancer, rather, would remain constant even after they ceased their asbestos exposure? 11 A There is not a substantive body of data to 12 13 define the answer to that question. 14 My understanding of the data that exists 15 suggests that short-term expense -- intense exposure 16 resulted in substantial increased relative risks, and those relative risks persisted after prolonged periods 17 18 of absent exposure. 19 That in conjunction with the data from Selikoff 20 studies showing that the relative risks for 21 asbestos-exposed individuals defined -- declined with 22 cessation of smoking was used to support the conclusions 23 that I've offered that asbestos exposure relative risk doesn't appear to decline over time. page 538 page 539 1 To the extent that that conclusion is correct, 2 in these populations of individuals one would expect 3 that the relative risk would remain constant following cessation of asbestos exposure, and that that relative 4 5 risk would be based on the accumulative asbestos 6 exposure prior to the time that they stopped being 7 exposed. 8 MR. SCHROEDER: Would you mark that one for me, please, ma'am? 9 10 Q The point of this chart, or one point of this 11 chart was to show that if individuals quit smoking, that 12 their relative risk for lung cancer would decrease based 13 on the years since quit, that you've listed here; is that a fair statement, that that is one of the points on 14 15 this chart? One of the points on this chart is that. 16 Α 17 Q Okay, thank you. A And it was intended to present that in a 18 19 relative context to other relative risks. 20 Q Okay. All right. And you have -- I notice on

```
your insulators here, some of your insulators go as high
21
22 as what appears to be 7 relative risk; is that a fair --
   if you go over to the left, is that a fair conclusion to
23
24
   derive from that?
page 539
page 540
         A It would appear to be that high, yes.
1
            What study was that; do you recall?
         A I would have to go back and look to see exactly
 3
4
    where that came from. It is likely that it may have
 5
    been a subgroup of a study.
         Q Did you make any assumptions on the declining
 6
7
    risk aspect of this chart as to the number of cigarettes
    per day or pack years for these categories of 1 through
8
9
    4, 5 through 9, or 10 plus?
10
            No. These were data taken from, I believe, the
11
    Surgeon General's reports on -- and it was either the
    Veteran's Study or the American Cancer Society CPS1
12
13
    data. But I can't remember which I used to generate
14
    that figure.
15
             I apologize for what was probably an obligation
16
    on your part to have waded through all of those graphs
    that were generated on the Cimino class. Some of them
17
18
    didn't make much sense.
19
        Q Some of them did, and I would like to ask you
about another one.
21
        A Sure.
22
             (Deposition Exhibit 10 marked.)
    BY MR. SCHROEDER:
23
        Q If you would take a look at what's marked as
page 540
page 541
1 Exhibit 10, can you tell me, Dr. Burns, that that's
    another one of the -- I used the phrase "Cimino," and
   I'm probably not saying that correctly, but since I have
 3
   lived with that, this is yet another Cimino chart, is it
 5
    not, that you used?
 6
         A I believe so.
         Q And this chart is --
 7
8
         A Well, let me be clear. It's another chart that
9
   I prepared in preparation for testimony.
         Q Fair enough.
10
11
         A I don't believe we ever used it.
            Fair enough. But you prepared this chart based
12
13
   on your review of literature that relates to the topics
14 noted on the chart; correct?
15
         A That's right.
16
         Q And you show us here, do you not, the relative
17 risk of lung cancer for asbestos-exposed individuals
18
    based on certain studies; is that a fair statement?
19
         A Certain studies and certain characteristics of
20 the populations and different studies, yes.
21
        Q And this is a relative risk of asbestos -- for
22
     asbestos exposure controlling for smoking; correct?
23
         A I don't believe so, no.
24
         Q Well, if you look over at the Selikoff group,
page 541
page 542
1 you have a relative risk for those greater than 20 years
 2
    exposure of seven. That certainly does not comport with
 3 the Selikoff conclusion.
     A Yes. As I said, I would have to go back and
 5 look at the sources. I don't recall exactly what I used
```

6 at this point. Q Okay. Well, looking at the two right-hand 7 8 columns --9 A This obviously is not a graph that ever went to 10 final, given the number of errors that are contained on 11 12 Q Well, in fact, though, you testified to it in 13 your deposition in the Cimino case, did you not? A I may well have. I'm just saying that I 14 didn't -- I don't recall the specific classifications 15 16 that I used to look at these risks. I don't believe that these risks were defined 17 18 by risks being controlling for smoking. 19 I believe these are risks of asbestos-exposed 20 populations in comparison to nonexposed populations 21 without control for asbestos -- for smoking, I 22 apologize. 23 Q The Selikoff study that you refer to on the right, is that the same study, whatever study it is, is page 542 page 543 it the same study just looking at people exposed less than 20 years and people more than 20 years? 3 A I'm not sure what you mean by the same study. It is the same -- I believe it is the same population. 4 It is likely that it is a different analysis of that population. Probably the one that was contained in the 6 New York, Annals of New York Academy of Sciences, where 7 Dr. Selikoff described the effects of asbestos without 8 9 defining the effect of smoking. In that same volume 10 Dr. Hammond and Dr. Selikoff together examined the 11 interactive effects. But both populations are presented. 12 I believe, and I would have to go back to check 13 14 to be certain, that these data may come from the study 15 of asbestos insulators, where the risks were categorized 16 independent of their asbestos exposure. But I would 17 have to go back and look. 18 Q Well, we know for a fact, do we not, that the 19 Hammond '79 study established for people who had roughly 20 20 years or so of asbestos exposure a 1, 5, 10, 50 21 relationship, do we not? 22 A In the analysis to control for cigarette smoke. 23 Yes. And the 5 was the asbestos exposure, was 24 it not? page 543 page 544 A The 5 was the asbestos exposure in those individuals who weren't exposed to cigarette smoke. 3 Q Correct. And isn't it true that for those 4 individuals who did not smoke in that cohort who were 5 exposed more than 20 years to asbestos exposure, that 6 their relative risk for lung cancer was actually close 7 to 7 or 8; that is, it was beyond 5? 8 A I don't recall data that specifically examined 9 that population. And I would have to go back and look. I've not seen a breakout of the nonsmokers with longer 10 11 exposure, at least that I recall. It may exist; I'm just not familiar with it by recall. 12 13 Q Are you aware of the study that you were 14 referring to when you did chart Exhibit 10? 15 A Do I have it sitting here in front of me? No. 16 Q No. Do you have it available at your office or

```
17
    someplace?
18
    A I believe that is the Selikoff study published
19 in the Annals of the New York Academy of Sciences. If
20
   that is the one, that is readily available.
         Q Is that the one where Dr. Hammond is the lead
21
22
     author on, that gave us the 1, 5, 10, 50 relationship?
23
     Or are you talking about a different study?
24
         A I thought I'd made that clear. But there are
page 544
page 545
    two descriptions of the asbestos insulator population
    presented in the Annals of the New York Academy of
    Sciences devoted to asbestos. Okay? That is the 1979
 3
    volume --
 4
 5
         Q Right.
 6
         Α
            -- that reflects that meeting. One is the
7
    study where Hammond is the first author.
8
         Q Correct.
9
         A That is the study that defines the interactions
10
    between smoking and asbestos exposure --
         Q Are you referring to that one here?
11
         A No. Where the 1, 5, 10, 50 numbers have been
12
    generated. There is also a study in that volume where
13
14
    asbestos insulators are examined as a group without
15 characterizing them by their smoking status.
16
         Q That's the study on death rates by Dr. -- I'm
17 going to ask you, is that the one by Dr. Seidman that
    dealt with death rates?
18
         A I believe that's a study by Dr. Selikoff as
19
20
    first author. There is also a study by Dr. Seidman on
21
    the same population that looks at some other aspect,
    which I think has to do with either future projections
22
23
     or some other characteristic that was of import.
             But my recollection, and it is a recollection
24
page 545
page 546
    that is foggy with time now, is that the numbers from
    this may have come from Selikoff's article that he was
 2
    the first author on rather than the Selikoff article
 3
 4
    that Hammond was the first author on.
 5
             (Deposition Exhibit 11 marked.)
    BY MR. SCHROEDER:
 6
         Q Let me hand you what's been marked Exhibit 11,
 7
 8
    and ask you, is that another one of the charts from your
9
    Cimino work? Do you recognize it?
10
         A I believe that it is, yes.
11
         Q And this chart predicts, does it not, the
12 percentage of persons exposed to, I take it, welding
13 fumes; is that what this intended to show us based on
14
    ILO stratification?
         A I believe -- I don't have a detailed
15
16
    recollection of what was done to generate this chart. I
17
    believe from the information provided on the chart, it
18
    is the percentage of individuals who were exposed to
19
    welding by their ILO classification.
20
         Q Why would that have been important in the
21
   Cimino litigation?
22
            I'm not sure.
         Α
            Did it relate to a question of whether there --
23
24
         A I should, perhaps, tell you that many of these
page 546
page 547
    graphs were generated by a member of my staff over a
```

very short period of time under the urgency of trying to 2 prepare for a deposition so that we would have some 3 information to look at. He ran large numbers of graphs 4 and combinations, many of which did -- had very little legitimate meaning in terms of how we would use them. 6 7 This one potentially could show a relationship to welding exposure. It does not. But potentially it 8 9 could have, I quess. 10 Q Well, you testified to this chart in particular 11 under oath, did you not, in a deposition? 12 A I don't have a recall of the deposition 13 sufficient to be able to tell you whether this was part of the deposition or not. It was likely that it was 14 provided as part of the materials for the deposition. 15 16 And if that likelihood was true, it's likely that we 17 went through it. Q All right. To the best of your recollection, 18 19 then, what is this intended to depict? 20 A This is intended to depict, to the best of my 21 recollection -- if it indeed is the data that I believe the title suggests that it is, and I don't know whether 22 that's true, to the best of my recollection, this would 23 be the percentage of individuals within each ILO 24 page 547 page 548 classification who reported exposure to welding. All right. Is it your understanding that 2 persons exposed to welding have increased asbestos 3 exposure because of the welding? 4 5 A No. It is my opinion, my reading of the literature, that people who are exposed to welding have 6 7 an independent source of abnormalities on their X ray, 8 and we were examining, I believe -- and this is a long time ago now, I believe we were examining whether that 9 effect would be evident in this population. 10 So for example --11 Q 12 The prevalence of -- well, go ahead. Α I'm sorry. For example, then, on Exhibit 11, 13 14 if you look at the ILO category of 1/0, would it be 15 correct to read this chart as saying that for all of those in this population in the Cimino case who had a 16 17 1/0 ILO perfusion, noted that more than 60 percent of them, perhaps even close to 70 percent of them, were 18 exposed to welding? Would that be a fair way to read 19 20 the chart? 21 Α This 1/0? 22 Q Yes. 23 A Well, it would be fair that they reported that 24 on -- into this data set. If -- again given the caveats page 548 page 549 that this is something that is, indeed, that analysis. 1 Q Okay. Did you have any reason at the time in 2 3 the Cimino case to doubt whether or not these persons 4 were actually exposed to welding fumes? 5 Α No. You said in the 1985 Surgeon General's report 6 7 that, "The abnormalities produced by smoking and those produced by asbestos exposure are usually quite 8 9 different on chest X ray once the disease process is 10 sufficiently advanced"? 11 A That's correct. 12 Q All right. And do you agree with that

13 statement today? 14 A I do. 15 Q And that you further stated that, "confusion 16 about X ray diagnosis is -- " I'm sorry, "in severe 17 disease is unusual"? That's correct. 18 Α And do you stand by that today? 19 Q 20 Α Q How do you define severe disease? 21 22 A Severe disease in general would be disease that 23 has a perfusion of 2/2 or greater. Q Okay. page 549 page 550 1 A Or alternatively, severe disease would be 2 disease that has resulted in a 40 percent loss of lung 3 function or greater. And you said in that report that, "The 4 5 radiographic changes associated with asbestos includes 6 small irregular opacities which commonly begin as a 7 radicular pattern in the lower lung fields and may 8 progress to diffuse interstitial densities throughout the entire lung with reduced lung volumes." 9 10 Do you stand by that today? 11 Α Yes. 12 You also said in that report that, "The 13 abnormalities that have been reported with COPD, include overinflation, prominence of lung markings, tubular 14 15 shadows, and in the presence of significant emphysema, 16 oligemia," which is a deficiency of the amount of blood 17 in the body, "and bullae"? 18 A Oligemia is actually deficiency of the amount 19 of blood in the lung. 20 Q In the lung, okay. And bullae. Do you agree 21 with that statement today? 22 A In general, yes, that's correct. 23 Would you agree with me that the studies upon 24 which Dr. Nicholson relied in his report dealing with page 550 page 551 the question of whether smoking increased the prevalence 1 of asbestosis among individuals exposed to asbestos 2 measured not clinical asbestosis but rather solely the 3 4 presence or absence of a parenchymal abnormality? 5 In most cases, those studies examined the chest X ray abnormalities using the ILO classification schema 6 7 which is not specific for asbestos, that's correct. 8 Q And most of those studies, virtually all of 9 them, use as a lower threshold the ILO classification of -- not of 1/1, as stated in your testimony for 10 11 clinical asbestosis, and as stated in the ATS document, 12 but rather the lower threshold of 1/0; is that correct? 13 A He used the lower threshold commonly used in 14 epidemiologic studies and that is supported by the 15 people -- by my understanding, at least, of how the ILO classification was intended to be used, okay, of 1/0, so 16 that you include all of those individuals who might have 17 18 abnormalities on their chest X ray. That's the 19 traditional epidemiologic approach using the ILO 20 classification schema. 21 He used that. And I believe, at least as I 22 recall his report, he conducted multiple approaches to 23 that, some of which looked at the prevalence of a

reading greater than that and others that looked at the 24 page 551 page 552 prevalence of readings by specific ILO classifications. Q You would agree with me that the studies on parenchymal abnormalities use a lower threshold of 1/0, 3 I think as you said, for epidemiological purposes, and 5 cannot be equated with the diagnostic standard that you 6 use for clinical asbestosis? 7 I don't agree with that statement. I think 8 that you're mischaracterizing a variety of things, and you're also mixing apples and oranges. The ILO 9 10 classification schema was developed for purposes of epidemiologic evaluation of population. It's 11 12 classification schema was intended to be very sensitive 13 so that you could pick up early diseases in those populations. It is used for that purpose. It is used 14 15 appropriately for that purpose with an ILO classification schema of 1/0 or greater. If one is 16 17 making a clinical diagnosis on an X ray, in general one does not use the ILO classification schema; one uses 18 19 evaluation of the X ray that says it's normal or abnormal and a description of the abnormality. 20 21 There are individuals who do that in 22 conjunction with describing an ILO classification. 23 that setting, when one is making a clinical diagnosis, 24 you're making the diagnosis based on being certain that page 552 page 553 1 there is an abnormality present. As I understand the ILO classification, that would translate to a 1/1. 2. So you're simply mixing apples and oranges in 3 4 terms of how this schema would be applied. MR. SCHROEDER: Would you mark that? 5 So is it fair to say based on that last answer 6 7 that the standard used for the clinical diagnosis of asbestosis is different from the standard applied in -for whatever reason, in the epidemiological studies that 9 10 deal with the prevalence of asbestosis among smoking 11 asbestos workers? 12 A I mean, you're asking me to compare things that 13 are apples and oranges. An epidemiological study is intended to examine a population. And you have got a 14 15 variety of different means by which you would classify 16 that population. One of which would be its X ray 17 classification. 18 In a diagnosis you are trying to define the 19 presence or absence of disease for an individual. And 20 it is uncommon to say, "I'm uncertain as to whether this 21 test is normal or abnormal." And therefore, what one 22 does is either make a decision that it is normal, after 23 careful review, or that it is abnormal after careful 24 review. page 553 page 554 So you are asking me to compare things that 1 don't fit in the same context in terms of how the 2 information would be used. I mean, I can't give you a 3 reasonable answer for that reason. 4 5 MR. SCHROEDER: Would you mark that one, too? The uncertainty you just referred to in your 6 7 last answer is reflected by the diagnostic standard of 1/0; is that what you mean by that?

```
9
            My understanding of the meaning of the
10
     classification 1/0 is that you believe that an
11
     abnormality is present, but that you are uncertain that
12
     it is present.
13
         Q
            Okay.
14
            It might not be present.
         Α
             All right. Thank you.
15
16
            How about one last short break before we get on
17
    the freedom bird here?
18
             MR. SCHROEDER: That would be fine. Off the
19 record.
             THE VIDEOGRAPHER: Off the record at 5:05 p.m.
20
             (Recess.)
21
22
             THE VIDEOGRAPHER: This marks the beginning of
23
    Videotape Number 5 of Volume 2 in the deposition of
    Dr. David Burns. We are back on the record at 5:14 p.m.
24
page 554
page 555
    BY MR. SCHROEDER:
 2.
         Q Dr. Burns, would you agree that in looking at
    the lung function test of total lung capacity that
 3
     smoking can actually cause total lung capacity to report
     a higher lung function than might actually be there
 5
    because of the smoking effect? Do you follow that?
 6
         A I don't follow that. The disease process --
 7
 8
         Q I'll withdraw the question. Let me rephrase
 9
     it.
             For a person who's exposed to both asbestos and
10
11
     smoking, isn't it true that the smoking component can
12
    actually cause the total lung capacity to appear to be
13
   normal when, in fact, it would have been reduced had
14 there been no smoking?
15
         A Yes. The disease effect produced by cigarette
16 smoking results in a loss of elastic recoil and
   increased lung volumes. And that may offset disease in
17
    other parts of the lung that result in a reduction in
18
19
    lung volume. That is not -- it's careful -- it is
20
    important for you to understand that is not offsetting
21
    effects in the same parts of the lung. That is two
22 different parts of the lung, both of which have been
23 damaged in different ways.
24
         Q But it's -- but if measured by total lung
page 555
page 556
    capacity, that measurement device can actually report
1
    normal when, in fact, an individual is jointly exposed;
 2
    there could be impairment to lung function?
 3
 4
         A That's correct.
 5
            And so if -- strike that.
 6
             And it's true, is it not, that in the absence
 7
     of cigarette smoking, asbestos exposure itself does not
 8
    result in clinically significant air flow obstruction of
9
    the sort seen with cigarette smoking?
10
         A That is correct.
11
         Q In the 1985 Surgeon General's report you said
12
    that, "If cigarette smoking contributes to the
    development of interstitial fibrosis in asbestos-exposed
13
14
    workers, the contribution is a minor one in comparison
15
    with the effect of asbestos dust exposure." Do you
16
   recall that?
17
        A Yes. And I believe we've already answered that
18 once before.
19
         Q Did we cover that one before? And you agree
```

20 with that? 21 A I agree with that still. I haven't changed 22 over the last 10 or 15 minutes. 23 Q Would you agree, Dr. Burns, that since all claimants who were compensated by the Manville Trust as 24 page 556 page 557 a condition of their being eligible for compensation had 1 2 to demonstrate prior asbestos exposure, that under those 3 circumstances, asbestos was a substantial contributing factor to the development of their disease? 4 A Well, I've not reviewed the population in the 5 Manville Trust. I'm not in a position to offer opinions 6 7 about the specifics of who is or is not in the Manville Trust population. And therefore, I can't really respond 8 9 to your answer. It is my understanding that there are some people in that Manville Trust who do not yet have 10 11 any injury, but simply have asbestos exposure, and are 12 in that database because they may subsequently develop 13 an injury. Which people are those? 14 Q I'm not -- as I said, I'm not conversant with 15 who is or is not in the Manville database. But it was 16 17 my understanding that at least some of the individuals who are considered have applied for and received a --18 19 some kind of certificate that says, "You have been 20 exposed to asbestos. You are part of this group. You 21 have no evidence of disease. But should you develop disease in the future, you will be compensated." 22 23 Now, I don't know for sure that they're part of 24 that group. I haven't looked at the group. I'm not page 557 page 558 conversant with it. And therefore, I'm not in a position to offer you an opinion. So I don't know whether everybody in the group is diseased. I don't 3 know the reality of what their asbestos exposures were. 5 And I can't really answer your question. 6 Q Is this a group apart from the persons who have 7 sought compensation for pleural plaques? 8 A I don't know. 9 All right. Well, you in the past have taken 10 the position that pleural plaques are not a disease 11 because there's no impairment; right? 12 A It is my opinion that pleural plaque itself 13 does not produce a functional impairment consistent with 14 producing functional limitation or disease. 15 Q All right. Would you agree that in an 16 individual who has lung cancer, and they have more than 17 one substantial contributing factor present, that is, 18 both significant asbestos exposure and smoking history, 19 that you as a physician cannot determine which factor in 20 that individual actually caused the cancer? 21 I think that that's not a fair 22 characterization. I think a more fair characterization 23 is that it would be my opinion that both made 24 substantive contributions, and they would make page 558 page 559 1 substantive contributions in proportion to the dose, 2 intensity and duration of exposure. Q And since both made substantive contributions, 4 both would bear some responsibility in the overall lung

cancer; is that your opinion? 5 A Yes. If there is a substantive asbestos 6 7 exposure and a substantive smoking history and the presence of lung cancer, yes, it is my opinion that both make a contribution to the disease occurrence. 9 Q Very briefly -- I know Mr. Molster wants to ask 10 11 some questions. 12 Let me ask you a couple of questions about the trust distribution plan. If you would pull that out. 13 14 It's one of the exhibits marked as Number 5 that's in 15 front of you, Dr. Burns. And I want to focus now on the disease in Categories 5 and 6. 16 I don't want to get these confused for the 17 court reporter here. 18 19 Q That's all right. 20 Did you find a copy? There it is on the very 21 bottom. Take a look at Category -- page 586 of the 22 23 document which is page number 2. The Category 5 in the 24 lower left column, would you agree with me that the page 559 page 560 claimant who has to file for Category 5 lung cancer has 1 to demonstrate at least 15 years of heavy occupational 2. 3 of exposure to asbestos-containing materials in employment regularly requiring work in the immediate 5 area of visible asbestos dust? Right? 6 That is what it reads, yes. 7 And would you agree with me that for any person 8 who has that type of heavy occupational exposure, that 9 asbestos would be sufficient to create a substantial 10 contributing factor to their lung cancer? 11 A I guess I'm a little confused by your language. 12 It would be sufficient to make it a substantive cause of the occurrence of their lung cancer, yes. 13 And that's whether or not they also smoked; 14 15 right? 16 Whether or not they also smoked. Α Q Okay. And would you agree with me under 17 18 Category 6 of lung cancers, that there is no -- there is 19 no requirement in Category 6 that you submit actual 20 pathology of your lung cancer claim; isn't that correct? 21 A I'm not quite sure what you mean. You have to 22 demonstrate medical report of the existence of a primary 23 asbestos-related cancer of the lung. 24 Q Correct. And there's no requirement in there page 560 page 561 1 that you actually submit pathology from your biopsy, is there? 3 How would you make that diagnosis otherwise? 4 Q I don't know. I'm asking you. 5 A The requirement to fulfill that would, with 6 unusual exceptions, require some pathologic 7 verification. 8 Q All right. You might not have to submit the slides, but 9 10 you certainly would have to submit the medical evidence 11 that that was true. 12 MR. SCHROEDER: Okay. I have a series of 13 questions I wanted to ask you about a couple of other 14 topics. But Mr. Molster has been sitting here patiently 15 here for two days now -- well, for a day, to ask

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questions. So I'm going to let him ask a few questions.
16
17
    I'm going to reserve my right for the record for the
18 opportunity to continue my exam on the other issues,
19
     which is something we'll just take up later.
20
             Thank you, Dr. Burns.
21
             MR. MOLSTER: Thank you.
22
                           EXAMINATION
23
     BY MR. MOLSTER:
24
         Q Good afternoon, Dr. Burns. As I indicated
page 561
page 562
1
     earlier, my name is Charles Molster. I'm with Winston
     and Strawn. I represent Philip Morris.
 2
             Just to make sure that we're on the same
 3
 4
    wavelength, I have come all the way from Washington,
 5
    D.C., to ask you some questions. As a result, I would
    be very appreciative if you would answer my questions
 6
 7
         not volunteer additional information that is not
    responsive to my questions. I suggest to you that my
 8
9
     questions for the most part are yes or no.
10
             In response to an earlier question today
11
    regarding our discussion regarding epidemiological
12
    studies, you used the term, quote, "causal inference,"
13
    end quote. Do you remember that?
14
         A I don't remember it specifically. I commonly
15 use that term.
16
            And that term means an inference of causation;
         0
17 correct?
         A That's correct.
18
19
            That term does not mean scientific proof of
20 causation, does it?
21
         A In some contexts it does. But in general it
22
    means that you are implying causality.
23
         Q And --
24
         A You are making a statement of causality, yes.
page 562
page 563
1
            An inference of causality?
 2
         A An inference of causality that is often in a
 3
     setting where you are stating that there is causality
 4
    present.
 5
            But it's true, is it not, Doctor, that that's
    different than scientific proof of causation?
 6
 7
         A It depends on the context of the statement.
         Q Now, you've previously discussed today public
8
9
    health action; do you remember that?
10
         A Yes.
11
         Q And you've also talked about scientific proof
12 today; correct?
13
         A That's correct.
14
            All right. It's true, is it not, that you
15
    agree that a different standard of causation supports
    the public health action as opposed to a standard of
16
17
    causation that rises to the level of scientific proof?
18
            There is an earlier --
19
            That's really a yes or no question, Doctor. If
20
     you could give me a yes or no answer, that's what I'd
21
     like. If you refuse to, we'll deal with it, but I'm
22
     asking you --
23
         A Are you constraining me to a yes or no answer?
24
         Q What I would like is yes or no. If you want to
page 563
page 564
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explain it, explain it. But what I would like is a yes 1 2. or no answer. A Yes. There are different standards of proof. 3 4 There is a threshold that one would use for being concerned. There's a threshold that would use for 5 taking public health action. 6 7 Q Yes. 8 And there's a threshold of scientific Α 9 certainty. 10 Q Now, the threshold that you would use for 11 taking public health action is lower; that is, a lower 12 standard of causation than one would use to describe 13 something as rising to the level of scientific proof; 14 correct? 15 A That's correct. 16 Q All right. Now, specifically as to whether or 17 not cigarette smoking causes disease, you agree that a 18 lower standard of causation supports public health 19 action as opposed to a standard of causation that rises 20 to the level of scientific proof? 21 A No. I believe that both of those standards 22 have been met. 23 Q That's not my question, Doctor. I didn't ask 24 you whether or not they've been met or not met. page 564 page 565 1 Could you read my question back, please? If you would listen carefully to my question, Doctor, and 2. only answer the question. 3 4 A I'm doing my best. 5 (Record read.) THE WITNESS: That is phrased, as I understand 6 7 it, in the present tense. 8 BY MR. MOLSTER: 9 Q No, I'm saying as a general matter, Doctor. It's not phrased as of today. I'm not asking you if 10 11 there's a difference as of today. Would you read -- do 12 you need it back again? 13 A I'm uncertain what your question is. Could you 14 clarify --15 Q We'll read it back again. A Could you clarify --16 We'll read it back. If there's a word you 17 don't understand, you tell me that you don't understand 18 19 it. But, Doctor, I've sat here all day long and seen 20 you repeatedly answer questions, by saying "I don't 21 understand. I'm not sure exactly what you're asking 22 me." And the questions have been plain as day. 23 So we'll read this one back. If that's your 24 response, fine, we'll deal with it. page 565 page 566 MR. GRUENLOH: Object --1 2 MR. MOLSTER: If you've got an objection, 3 object to form. No speaking objections, please. 4 MR. GRUENLOH: I object to that 5 characterization. 6 MR. MOLSTER: Fine. Would you read it back? 7 (Record read.) 8 THE WITNESS: I believe the standard for both 9 has been met. 10 MR. MOLSTER: Yeah, but that's not my question. 11 I move to strike as nonresponsive. I'm going to

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discontinue this line of questioning because of your
12
13 answer. I'm going to go to the judge and ask for we
14 come back to take your deposition, and I'm going to ask
15 that it be at your expense or at the expense of
16
    plaintiff's counsel.
17
             THE WITNESS: I have pointed out that I've
18
    asked you for clarification --
19
            MR. GRUENLOH: Don't engage in this discourse,
20 Dr. Burns.
21 BY MR. MOLSTER:
22
    Q You're not an advertising expert, are you,
23 Doctor?
24
            MR. GRUENLOH: I'm sorry, hold on one second.
page 566
page 567
1 Could you tell me what time it is? What time do we have
   on the record?
2
3
             THE VIDEOGRAPHER: I show 5:28.
             MR. GRUENLOH: Thank you.
5
    BY MR. MOLSTER:
     Q You're not an advertising expert, are you,
 6
7
    Doctor?
8
    A I have expertise in the application of tobacco
9 advertising relative to smoking behavior.
10
        Q You're not an advertising expert are you,
11 Doctor?
12
        A I have defined what my expertise is that
13 relates to expertise in advertising. I am not a
14 practitioner that develops advertising for use.
15
         Q You're a medical doctor; correct?
16
         A I'm a medical doctor.
17
         Q You never worked in an advising agency, did
18 you?
         A I have never worked in an advertising agency.
19
            You're not media expert, are you, Doctor?
20
         A I have substantial expertise in the use of
21
    media for public health purposes. I'm not someone who
22
23
   has exclusive training or function in media.
24
         Q Do you hold yourself out as a media expert?
page 567
page 568
        A I hold myself out as a media expert relative to
1
    the examination of the impact of media for tobacco
 2
 3
    control issues and have received grants for that
 4
    purpose.
5
     Q Do you hold yourself out as an advertising
 6 expert?
7
     A I've told you my expertise relative to
8 advertising.
9
    Q My question is, do you hold yourself out as an
10 advertising expert?
11
         A I have received grants for purposes of
12 examining advertising, and that is the basis of my
13 expertise, the examination of those issues.
14
     Q Do you hold yourself out as an advertising
15 expert, Doctor?
             MR. GRUENLOH: Objection; asked and answered.
16
             THE WITNESS: I hold myself out as an expert in
17
18
   advertising relative --
19 BY MR. MOLSTER:
20
        Q Have you --
21
        A Please let me finish. Relative to the
22 investigation of the impact of advertising on smoking
```

```
behavior and have received grants based on that
23
24 expertise.
page 568
page 569
            Are you holding yourself out as an advertising
1
     expert in this case?
2
     A I am holding myself out as an expert on the
 3
 4
     impact of tobacco advertising and counteradvertising on
 5
     smoking behavior.
 6
         Q In this case?
 7
            In this case. I don't know whether that
     expertise will be called for.
 8
9
         Q We have spent some time today talking about,
    you made reference both in your report and in your
10
11
    opinions today to epidemiological studies; is that
12
    correct?
13
         A I have used that term.
         Q Epidemiological studies use statistics to try
14
15 to investigate the lengths between diseases and the
16
    factors which may cause those diseases?
         A All studies scientifically, in general, use
17
    statistics. Epidemiologic studies use epidemiologic
18
    approaches and then apply statistics to the data that
19
20
    they generate.
21
         Q Can you give a yes or no? Are you unwilling to
22
    give a yes or no answer to my question?
23
         A I think your question mischaracterized
     epidemiologic studies. I'm simply trying to be clear.
24
page 569
page 570
            A relative risk is the statistical measure
1
     which expresses the findings of an epidemiologic study;
 2
    isn't that true, Doctor?
         A No. It is the epidemiologic measure that
 4
     compares the death rates in two populations.
 5
         Q Now, Doctor, you agree, as I understand it,
 6
 7
    that in your view, the lung cancer risks caused by
 8
    cigarette smoking are proportional to the intensity and
9
    duration of the exposure to cigarette smoke; is that
10
    correct?
11
         A That's correct.
12
         Q And is it also your view, Doctor, that lung
13
    cancer risks also increase directly in proportion to the
14
    intensity and duration of asbestos exposure?
15
         A That is also correct.
16
            Okay. Now, is it -- it is also true, then,
17
    isn't it, Doctor, that any relative risk model regarding
18 the health effects of smoking and tobacco would require
19
    adequate consideration of at least the following
20
    information regarding the individuals that make up the
     population being modeled: Number 1, the length of time
21
    of exposure to asbestos. Number 2, the level of
22
23
     exposure to asbestos during that length of time. Number
24
     3, the length of time that the individual smoked
page 570
page 571
     cigarettes. And Number 4, the amount of smoking during
 1
 2
     that time that the individual smoked cigarettes?
             MR. GRUENLOH: Object to the form of the
 3
 4
     question.
 5
             THE WITNESS: The answer to the question is no.
 6 It is possible to mathematically model populations based
     on data more limited than that you have available in
```

8 9 MR. GRUENLOH: Counsel, yesterday when you weren't here we reached a stipulation that we were only 10 11 going to go until 5:30 today. I'm going to hold you to that. I apologize that your counsel didn't give you 12 13 enough time, as I see that you have more questions. MR. MOLSTER: I've got a lot more questions. 14 MR. GRUENLOH: We're going to go ahead and 15 16 conclude the deposition. 17 MR. MOLSTER: You can get up --18 MR. SCHROEDER: Just for the record, the 19 stipulation was that we wouldn't go past 5:30 based on his time. But we didn't stipulate that the deposition 20 would be concluded. And so we have no agreement we 21 22 would finish the deposition. 23 MR. GRUENLOH: Let me also put a statement on the record at this point. In the interest of time and 24 page 571 page 572 1 efficacy I've tried to limit my objections during the course of this deposition to a minimum, despite the fact that defense counsel have often asked vague questions 3 and asked those same questions over and over again to 4 5 the point that it's bordered on harassment. 6 Prior to today the defendants postponed this 7 deposition with little or no reason at least three or 8 four times. And the correspondence between counsel bears that out. It is our position that defendants have 9 spent much of their deposition time on issues which have 10 11 been brought in Dr. Burns' prior depositions and 12 testimony, including issues of addiction, low yield cigarettes, and the processes through which Surgeon 13 14 General and scientific field reaches consensus on the issues of tobacco and disease causation. 15 So again I object to the scope of the 16 17 defendants' questions and defendants' conduct in this deposition. Specifically Mr. Bernick's practice of 18 continually interrupting the witness and his attempts to 19 20 intimidate this witness. 21 I think that the transcript of this proceeding, 22 when it's looked at in its entirety, will bear this out 23 and will reflect that this objection -- all of these objections are well grounded and based in fact. 24 page 572 page 573 1 In light of these facts, I object to any suggestion that the defendants be given any more time in 2 3 addition to the two days that they have already had to 4 examine Dr. Burns. 5 MR. SCHROEDER: I'm not going to spend any more 6 time arguing on the record. We can argue with the 7 judge. 8 MR. GRUENLOH: Sounds good. 9 MR. SCHROEDER: Our position is the deposition 10 is not over, and we'll leave with it that. Thank you, Dr. Burns. 11 MR. MOLSTER: I have more questions. You can 12 13 get up and leave if you want to get up and leave. 14 let's just stay on the record. I'm going to put a 15 couple more questions on the record. 16 MR. GRUENLOH: You're going to ask questions 17 without the witness? 18 MR. MOLSTER: I'm just going to put on the

```
record some of the topics that I would go through if you
19
20
   weren't getting up and leaving. You can get up and
21 leave. I mean, I can't stop you from doing that.
22
            MR. GRUENLOH: You know, Counsel, you weren't
    here yesterday when we reached that stipulation. You
23
24 came in halfway through the day today. You're not even
page 573
page 574
    aware of the conduct that went on yesterday.
1
            MR. MOLSTER: I didn't come in halfway through
 2
 3 the day today.
             MR. GRUENLOH: Yes, you did.
 4
             MR. MOLSTER: No, that's not true. I was here
 5
 6
   before the deposition started.
 7
             MR. GRUENLOH: If you want to --
8
             MR. MOLSTER: Then I went to do a conference
9
   call with Judge Gold. So that's a direct
    misrepresentation you just made on the record about me
10
    coming in halfway through the day today.
11
12
             MR. GRUENLOH: I don't know what time you came
13
     in --
             MR. MOLSTER: I came in as soon as we got off
14
15 the phone with Magistrate Gold.
16
             MR. GRUENLOH: Well, it was after the
17 deposition had started. And you certainly weren't here
18 yesterday.
             MR. MOLSTER: Let the record reflect that
19
20 obviously counsel and the witness are leaving the room
    over our objection, and we will take it up with the
21
    court. Okay. Thank you.
22
23
             MR. GRUENLOH: In accordance with the
24 stipulation we reached.
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page 575
             THE VIDEOGRAPHER: This concludes Volume 2 in
1
    the videotape deposition of Dr. David Burns. The number
    of videotapes used was five. We are going off the
 3
 4
    record at 5:36 p.m.
 5
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    //
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page 575
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9
             I, DAVID M. BURNS, M.D., do hereby declare
    under penalty of perjury that I have read the foregoing
10
11
    transcript; that I have made such corrections as noted
    herein, in ink, initialed by me, or attached hereto;
12
13 that my testimony as contained herein, as corrected, is
14 true and correct.
        EXECUTED this _____ day of ____
15
16 2000, at _____
                        (State)
(City)
17
18
19
                       DAVID M. BURNS, M.D.
20
21
22
23
24
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1 STATE OF CALIFORNIA )
                                                : ss
2 COUNTY OF SAN DIEGO
3
             I, the undersigned, a Certified Shorthand
 4
 5
    Reporter of the State of California, do hereby certify:
 6
     That the foregoing proceedings were taken
 7
    before me at the time and place herein set forth; that
    any witnesses in the foregoing proceedings, prior to
 8
9
    testifying, were placed under oath; that a verbatim
    record of the proceedings was made by me using machine
10
    shorthand which was thereafter transcribed under my
11
12
    direction; further, that the foregoing is an accurate
13
    transcription thereof.
             I further certify that I am neither financially
14
15 interested in the action nor a relative or employee of
16
    any attorney of any of the parties.
17
           IN WITNESS WHEREOF, I have this date subscribed
18
    my name.
19
20
    Dated: _____
21
22
23
RENEE KELCH
                          CSR No. 5063
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